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Education and Quality of Life

in

Oral and Pharyngeal Cancer Patients

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2006

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Abstract

The psychosocial intervention in cancer patient management has been shown to reduce anxiety effectively, but no assessment has been made of the effect on health related quality of life (HRQOL). The aims of this project were to examine head and neck cancer patient's level of information and assess anxiety level and HRQOL in an attempt to recommend the educational psychosocial support needed for oral and pharyngeal cancer patients.

The first part of this research audits the patients' information support (as part of the psychosocial support) and preferred format for additional information material. A locally developed questionnaire was applied to three groups of oral disease patients; the multidisciplinary team approach was significantly better in informing oral and pharyngeal cancer patients. The survey also confirmed the patients' preference for written format information materials and the low preference for the computer technology as a source for health information.

The second part of the study aimed to assess oral and pharyngeal cancer patients' anxiety level and HRQOL. The results showed that patients have levels of HRQOL comparable to those previously reported in similar studies, although patients had higher level of anxiety.

The third section correlates the anxiety scores from the HADS to HRQOL scores; the HADS-Anxiety scores were significantly correlated to the SF-36 scores at the preoperative stage and to the EORTC H&N35 scores at the postoperative stages. Predictability equations were formulated for the HRQOL domains scores using the HADS score.

The final section was a semi-structured interview with 30 head and neck cancer patients and their families. This was a cross sectional study with the aim of examining the relationship between information, educational level, anxiety and HRQOL.

In conclusion, oral cancer patients required more sophisticated gating of information about disease management. There was a significant correlation between anxiety scores with HRQOL scores; however the high anxiety scores suggested that patients' education should include methods of anxiety control. Patients' perception of good psychosocial support can improve their HRQOL.

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Introduction

Psychology is one of the factors that define health as proposed by the World Health Organization (1947). Its assessment has been advocated as part of the general health assessment (Wan et al. 1997) and Tim McElwain (a leading figure in oncology in the U.K. during the 1980s) often said that patients, who feel better, do better (Mossman et al. 1999b).

In the last century, the success and quality of oncology therapeutic intervention in clinical and health services focused on traditional indicators such as prolonged survival, retardation of the disease process, and control of major physical symptoms and this will remain central in cancer clinical research. However, in the last 20 years quality of life has emerged as a crucial aspect in the assessment process of emerging therapeutic intervention and clinicians need to consider the patient's prospect in how the treatment is going to influence their functional, psychological, and social health (Aaronson 1991).

Oral and pharyngeal cancers are amongst the ten most common cancers in the world. The WHO assesses that oral cancer as the 3rd commonest malignancy among males and 6th commonest in females (Langdon 1995). In the UK head and neck cancers account for less than 4% of all solid malignant cancers (Hindle et al. 1996).

Despite the fact that cancer is more treatable today, there is still a persistent fear that attends a diagnosis of cancer; fear of death, pain, loss of attendance/independence, and the suffering associated with cancer progression in palliative care (Dolbeault et al. 1999).

Moreover, patients with head and neck cancer have to struggle with many losses such as normal facial appearance, speech, and sensation. This may cause an enormous threat of

self image, confidence and identity which may lead to anxiety or depression. This is because changing the individual's hidden image of their faces is very difficult and adapting to new changes can be a very long process. Also, removal of part of the jaw bone or tongue may affect the patient's ability to communicate efficiently, and with deficient facial expression to support verbal communication patients can develop a social phobia and isolation (Kugaya et al. 1999).

It is true that the diagnosis of cancer and its treatment may initiate a period of confusion, uncertainty and psychological distress. Improvement in diagnostic methods and recent advances in therapeutic modalities give a better chance for cancer patients today to live longer, however, there is still disease symptoms and treatment side effects (Rapoport et al. 1993). Therefore, disease related morbidity is a significant factor in the evolution of competing interventions and in justifying decisions to provide supportive care.

Anxiety is an expected emotional response for appropriate concern about medical disorders and it has an adaptive value for most individuals most of the time. However, patients sometime lose control over anxiety to the extent that it causes physical or social impairment and becomes maladaptive. There is a substantial number of head and neck cancer patients at risk of developing mood disorder during the first year of cancer diagnosis (Hammerlid et al. 1999a).

The government policies emphasize the role of patients' education in health care. Research has shown that a majority of patients, regardless of their sex, age, and deprivation, want as much information as possible (Meredith et al. 1996). Also, health professionals increasingly recognise that people facing decisions about their health care need good quality information relevant to their treatments and outcomes.

The government advocates patients' involvement as partners in health care. The increase in office-based procedures and ambulatory surgery coupled with shorter hospital stays necessitate that patients assume greater responsibility for their own care before and after procedures (Krouse 2001). Patients' attitudes of paternalistic health care must shift to an attitude of full acceptance and encouragement to share responsibility of treatment choice, and day to day self-care. Surgeons need to evaluate patients' needs and ability as well as understand the emotional aspect of learning; and invite patients to discuss information provided. Also, they need to recognize that people learn in different ways, and acknowledge that efficient learning calls for interaction between the patient and the doctor.

Health authorities have acknowledged the need for patient's education, and developed different departments and organisations to provide health consumers with quality information. However, the underlying policies for providing that quality information are complicated by barriers associated with "teaching" on the side of healthcare providers and "learning" by the health consumers. This is recognized in research reporting patient dissatisfaction with the amount of information provided (Coulter et al. 1999, Fallowfield et al. 1995, Hope et al. 2000, Leydon et al. 2000, Meredith et al. 1996, Semple et al. 2002). However, it is difficult to know whether patients are dissatisfied with information levels because the information given is not enough or they are highly stressed and the information provided is not helping to control their anxiety.

Medical research and medical practice are synergistic and complementary with a common aim of increasing the survival rate and improving the quality of life of cancer patients using the best available therapeutic modality (Meunier 1997). Psychosocial intervention research and their emphasis on the emotional, social, and functional aspects of well-being may result in remarkable improvement in patients' health related quality of life

(HRQOL) and better assessment of the competing therapeutic modalities. There is considerable heterogeneity in methodology among psychosocial interventions used in cancer patients; however, there appears to be little agreement to what type of intervention will provide maximum benefit for any individual patients. This is because cancer patients are exposed to different psychological stressors before, during and after treatment; also patients vary in their age, gender, social/cultural background, education level, financial situation and family relations. Furthermore, different methods of psychosocial intervention have been applied sporadically for different primary cancer sites with little consistency on the objectives of the interventions (Fawzy 1999, Owen et al. 2001a). Therefore, adoption of more uniform approaches to quality of life assessment can provide a valid evaluation to the impact of psychosocial interventions and facilitate comparisons between different types of interventions.

The first chapter in the present study will assess the effectiveness of information delivery system to oral and pharyngeal cancer patients, and their preferred format of additional information; the second chapter will look at oral and pharyngeal cancer patients' HRQOL with more emphasis on anxiety level as it is likely to be affected by level educational psychosocial support. The last chapter will look into the relationship between patients' perception of psychosocial support including level of information about their disease and patients' health related quality of life.

Chapter 1

1. Patient satisfaction and preference for information (Survey)

1.1 Literature review

1.1.1 Information patients need

Cancer patients are a diverse population and their needs for information varies considerably depending on many factors such as their preferences, coping method, age, sex, type of information provided and stage of disease management (Leydon et al. 2000); thus it is important to customise information to individual patients' abilities and needs at different stages of treatment (Newell et al. 2004).

Common themes of information patients need to know are diagnoses; treatment options; the chance of cure and possible side effects. In cancer, the overwhelming majority of patients wish to know if they have cancer, what are their chances of cure, and all the possible side effects of treatment. Other information patients may wish to know are the nature of the procedure, its purpose, the outcomes and risks, the options and alternatives, what would happen to them in the near future, overall care available, key contact names and phone numbers in the treatment centre (Fallowfield et al. 1999, Harris 1998, Hope et al. 2000, Humphris et al. 1999, Meredith et al. 1996, Ream et al. 2003). Due to the facial disfigurement and physical impairments that may result from treatment in head and neck cancer patients, this group of patients have concerns about specific issues such as social relationships and self esteem.

Patient education often starts in the hospital during their consultation visit to the multidisciplinary clinic (consultants, nurses, dietician ....etc) and during hospitalisation; however, education is a continuous process and needs to continue thereafter in the outpatient setting, at home with family members and friends (Jones et al. 2001, Leydon et al. 2000, Little et al. 2004). Patients realised that their provision for information was

different during the course of treatment. Research showed that provision of information is part of an ongoing process, and for maximum benefit the professionals need to use their communication skills for continuous assessment of patients' need for information and support during care; and reinforce by repetition and discussion (Butow et al. 1997, Hope et al. 2000). This observation complements the Lazarus theory that describes patients with a chronic illness who are continually appraising their symptoms, pains, disease progression with respect to their well-being and survival, and coping accordingly (Lazarus 1991).

The strategy of spacing the appointments apart or discussing treatment in more than one session is considered necessary. This arrangement will ensure that patients have more time to think of the treatment options provided and discuss it in a different environment and a more suitable time. It is not uncommon for patients to come back with new questions and to bring a relative in the next appointment for support, and help memorising information provided (Leydon et al. 2000). Informing patients of what to ask their doctors during consultation visits will improve the effectiveness of communication and satisfaction without increasing the consultation time (Little et al. 2004).

1.1.2 Current status of oral and pharyngeal cancer patients education

The Department of Health Cancer Patients Survey (Health, 2002) of 6500 hospital patients reported overall high levels of satisfaction with the provision of care and information. However, patients under the age of 65 years were more critical and dissatisfied with many aspects, including information about the diagnosis, treatment and side effects. In addition cancer patients who scored high psychological distress were notably less satisfied than were those with lower distress scores (Shilling et al. 2003). The King's Fund study on head and neck cancer patients reported that patients had a mixed experience with receiving appropriate information (Edwards 1998). However, Fallowfield

et al (1999) in a large study for different types of cancer patients, including head and neck cancer patients, have reported that a number of patients leave the consultation room suspicious about the diagnosis and prognosis, unclear about the management plan and uncertain about the therapeutic objectives of treatment (Fallowfield et al. 1999).

Among the public, studies in the USA have demonstrated that there is a general lack of knowledge concerning the signs, symptoms and risk factors of oral cancer and demonstrated the need for vigorous health education and health promotion to increase public knowledge (Horowitz et al. 1996). In the UK, very little evidence has been reported in the literature of knowledge held by the public about the incidence, aetiology, signs and symptoms of oral cancer (Naila et al. 1995). However, a recent survey of the UK public knowledge of cancer shows a significant deficiency in public cancer knowledge (Adlard et al. 2003).

Risk factors for oral and pharyngeal cancers include tobacco smoking, alcohol abuse, old age and auto-immune diseases to name a few; but the two major preventable ones are tobacco smoking and alcohol abuse. A recent study reported that tobacco smoking is the only perceived risk factor by people participating in oral screening programs (Hay et al. 2002). Researchers have suggested that the reason behind this situation may be the deficiency of information materials for oral and pharyngeal cancers; and most of the present materials are written at a reading level too high for many target groups, especially those with lower levels of education (Chung *et al.* 2000).

1.1.3 The advantage of educating patients:

The need to educate patients about treatment prospective is derived from concern about issues like treatment ethics, improving patients' trust and compliance with treatment,

ensuring informed consent, improving patients' satisfaction, encouraging patients to change their behaviour; enabling patients to anticipate problems, assisting rehabilitation in patients with curable cancers and avoiding unnecessary distress (Cawsey et al. 1997, Crawford 1994, Stafford et al. 2001, Thomas et al. 2000). A randomised controlled trial by Little et al (2004) on patients visiting GPs shows that education can empower patients and improve their satisfaction and perception of consultation (Little et al. 2004). Also, by encouraging patients to set and maintain realistic goals concerning their prognosis and treatment process it is possible to narrow the gap between individuals' expectations and the perceptible outcome (Wan et al. 1997).

Patient education is central for acquiring informed consent (Cawsey et al. 1997). A valid consent entails that the patient has been provided with a satisfactory amount of information to enable him/her to agree to the proposed treatment plan; this includes the possible treatment outcome, the side effects, possible complications as well as alternative treatments including no treatment. Information gives patients the feeling of cognitive control of their situation; this means that patients will have the autonomy to participate as a partner in the decision-making process (Semple et al. 2002). However, it is important to note that information is not the only factor that influences patient decision about their treatment options. Other factors include the patients personal experience, attitudes and beliefs as well as family, friends, media and other health professionals (Richards et al. 1995).

Although a direct positive relationship between patients' preference for information and their desire for decision-making involvement have been reported (Timmermans et al. 2004); not all patients desire more information than what has been given wish to participate in decision-making process (Semple et al. 2002). Some find additional information

confusing, others look for reassurance in the consultation visit to maintain hope and fear of uncovering more traumatic information (Leydon et al. 2000, McPherson et al. 2001). Butow et al (1997) found that cancer patients want less involvement in decision-making when their conditions deteriorate in the process of treatment (Butow et al. 1997). This fine balance of control over the flow of information gives the patients their psychological independence and feeling of control. Furthermore, information seeking behaviour is but one strategy of problem-focused coping methods many patients use to manage their stress (Van Der Molen 1999). One should not overlook the stress effect on cancer patients' cognitive ability as stress will make it difficult for the patient to remember all the information provided and decide on the best course of action (Fallowfield et al. 1999).

A high level of anxiety has been reported in newly diagnosed cancer patients, and many develop psychiatric disorders within the first 2-3 years of diagnosis (Fawzy 1999, Maguire 1995, Mossman et al. 1999a). Information can help people manage their health problems and stresses that may result from the disease and its treatment or the confusion that may arise with cancer diagnosis (Van Der Molen 1999). There is no doubt that correcting practical uncertainties of cancer therapy improves patient satisfaction and reduces a significant amount of the associated psychological distress (Thomas et al. 2000). Patients who receive preoperative information about disease and treatment were reported to be less likely to suffer anxiety symptoms or experience depression postoperatively (Fallowfield et al. 1995). Also, a positive association has been reported between depression/anxiety and the need for information (Mesters et al. 2001).

Family members have a role in providing support and care to the patient at home, therefore, their routine life will be affected; providing them with information may help in understanding the disease and its consequences, and how to cope with the new situation

(Van Der Molen 1999). Many cancer patients felt that it is useful at least for family members to receive written hospital information (Hope et al. 2000). Structured educational intervention has been found to offer the greatest potential for patients and their families who are newly diagnosed with cancer or are in the early stages of treatment (Fawzy 1999). The validity of this form of intervention supported by others for its efficiency over a short period of time from diagnosis; however, its power as a single form of support in the long term was questioned (Chumbley et al. 2002, Jones et al. 1999, Leydon et al. 2000, Pruitt et al. 1993).

The rehabilitation outcome in cancer management is related to the type of treatment received. One of the goals in quality of life research is to give a description of the recovery course so patients can assess their own health status and rehabilitation adequately (De Boer et al. 1999, Mossman et al. 1999b). Self management of chronic illness is central in the process of transition from one life style to another; this can be a structured process of education that involves the daily experience of trial and error to know the personal limitation. Additionally, patient education emphasises the importance of prevention and early detection of the disease. This hopefully will result in more active individual participation in the health system by increasing personal competence in self care (Heaney et al. 2001).

1.1.4 Standards for patients education

The UK government has a growing awareness of the importance of empowering patients with information. In 1993 the NHS Survey Commission studied the interaction between hospitals and patients. One of their recommendations was to provide patients with written information about conditions, procedures and post operative care (Coulter et al. 1998). The Expert Advisory Group report to the chief medical officers for England and

Wales recommended that "Patients, families and carers should be given clear information and assistance in a form they can understand about treatment options and outcomes available at all stages of treatment from diagnosis onwards" (Calman et al. 1995). The Health Act 1999 puts information for patients and the general public high on the NHS agenda, and lays down the national standards and defines models through a series of National Service Frameworks (Duman et al. 2000). The Patient Liaison Group from the Royal College of Surgeons in England went further and stated that the patient has the rights to have staff that understand his anxious feelings and vulnerability which may affect the way he/she behaves (Patient liaison Group 2003).

1.1.5 Factors may affect patient's education:

The strategies of providing information to patients are complicated by many factors. They involve both personality and attitudinal characteristics of patients and their health carers, together with difficulties created by the cancer care delivery systems (Fallowfield et al. 1999). In the education process there are two principal characters, a teacher and a learner. The learner is the person (i.e. patient) active in the construction and development of new knowledge and skills. The teacher (health professional) on the other hand is the person who activates and supports the learner contribution to the process of education. It is the teacher who should recognise the learner needs and preferred style; and make use of the many different ways available to ensure the efficiency of the education process. The teaching methods are moving from the slow rigid way of spoon feeding to a more dynamic interactive interplay between the teacher, the learner and a learner based agenda. This highlights the fundamental idea of education as a self generated process; health care provider can help setting objectives, providing guidance, support, and

performing continuous evaluation, and patients must use what is available for them to know more about their disease and its management (Babcock et al. 1994).

1.1.5.1 The health consumer (patient)

People are different in their needs for information and in their capacity to mentally absorb new knowledge, also in their physical ability to change. Not to consider these factors in educating patients is ignoring the diverse nature of human being, and an attempt to fit patients to what we know or have rather to what is available. It is the learner at the end who has to make his/her own sense of what is being learned. The followings are important factors to consider in planning and implementing patient's education as they may influence the style or the content of the discussion and ultimately the outcome from the consultation visit.

1- Aroused interest or motive:

Although, it is universally agreed that information is an important part of cancer care, the issues of how much, in what form and when will depend mainly on the individual patient's approach to seeking information (Mossman et al. 1999a). Motivating factors for cancer patients to learn more can be divided into extrinsic and intrinsic motivators. Extrinsic motivators are those where satisfaction of need will come from outside the person. This type of motivation is rare in health education and may be considered ineffective for motivating cancer patients. In intrinsic motivators the reward here comes in the form of inner satisfaction and feeling of accomplishment after overcoming a problem or acquiring knowledge (Babcock et al. 1994).

It is not uncommon to have intrinsic motivators in cancer patients; a useful motivator reported to be associated with desire for information is patient's attitude (Leydon

et al. 2000). Patient's attitude from successful past experience such as the past experience of good management of chronic illness affecting the patient or his relative can be used to motivate patients to have confidence in themselves as learners, to acknowledge their chances of success and have the strength to make an effort to change.

The concept of partnership can be a motivating factor. Teamwork was found to be successful in situations where it has been encouraged. When patients feel that they are a member of a cooperative team, the outcome is often better than when a number of individuals are working in isolation. Additionally, head and neck cancer patients are going to have a major operation that will affect many aspects of their life; this should be a strong motive for them to learn new behaviours or improve existing one to cope with the challenges during the rehabilitation phase.

2- Patient's skills:

Learning is a skill and demands continuous practice in order to become more autonomic and efficient. Less skilled people will consume a great deal more energy and time than skilled people and are consequently considered less efficient (Babcock et al. 1994). The use of additional information materials in the form of videotapes will help to overcome this factor in less skilled people (Foltz et al. 1999).

Some patients may feel that they are getting too old to learn and change, or may fear that they appear dense relative to others. Others assume that asking a lot of questions is violating their current role as a good patient (Leydon et al. 2000). Therefore, it is important to assess the patients' skills, attitude and cognitive ability to know if the patients can grasp the meaning of information provided and perform the required behaviour.

3- Maturity:

Most patients attending the head and neck oncology clinic are fully mature adults and capable of making decisions of their concern, even teenagers get mature earlier as a consequence of the disease. However, a small group of patients are very young or mentally challenged; this group of patients needs more attention to communicate, and their family cooperation in this case is essential. Also, when adult patients agree to participate in learning activities they expect to be treated in a way that promotes self-esteem and self confidence and they expect to be able to make use of what is learned more or less immediately.

4- Level of wellness:

The stage of acute illness is frequently accompanied by pain, confusion, physical disability and fear. Patients in the acute illness stage will direct most of their energy to cope with the psychological trauma, and their learning needs are very limited (Coulter et al. 1999). During recovery and after removal of the immediate threat, patients are more stable and willing for proper education.

Also type of disease may influence type of information needed. In cancer, where patients are actively involved in the management, patients wish to see more individualised information (Ream et al. 2003); however, general public smokers prefer non-tailored letters that contain advice on behavioural changes than tailored letters with input aimed at boosting motivation, confidence and self efficacy (Lennox et al. 2001). Also, cancer patients with poor prognosis and those having palliative treatment were less likely to ask for detailed information and participated less in the decision-making process (Fallowfield et al. 1995).

5- Physical limitation:

There are a considerable number of cancer patients over the age of 65 years. Associated with this age group is the risk of physical impairment such as poor eyesight or hearing deficiency or communication difficulty (especially in head and neck cancers). Such physical impairments are important factor that may hold them back from learning and need to be accounted for in the education process.

6- Socioeconomic forces:

Patients from affluent areas tend to wish for more information than those from deprived areas (Gatherer 2000, Meredith et al. 1996). Patients before and after the treatment are in a state of stress, one way of minimising this stress is by having control of the surrounding environment. Individuals with financial and emotional resources can pay for services and rely on support systems to sustain themselves through recovery. Individuals without such resources are much more deficient and at risk for reaching less than their potential level of functioning.

7- Educational level:

General knowledge of health is often related to a patient's level of education. The higher the level of education, the greater the knowledge base and the more likely the patient will engage in health promotion behaviour. Furthermore, patients with a high level of education are expected to have large vocabularies and consequently are more likely to comprehend what the health professional is saying. Type of newspaper has been used before as indicator for general knowledge; research reported that broadsheet newspaper readers desire more information than tabloid newspaper readers (Gatherer 2000, Jones et al. 1999). Moreover, patients are exposed repeatedly to television programs and other media

about cancer. This makes communication with the overly informed and sometime-misinformed patients an increasing problem.

8- Adaptation:

Adaptation or adjustment is the process that patients involve in order to counter stress and reduce or neutralize its effects during the acute changes from the disease or its treatment. Patients' use two main coping methods for that, problem focused techniques to promote recovery and restore function; and emotion focused techniques to control and protect them from the psychological trauma (Babcock et al. 1994). Many patients and their families have repeatedly reported that their anxiety level and other concerns interfered with their ability to comprehend materials that would be quite understandable under normal circumstances (Fallowfield et al. 1999).

People sometime protect themselves when under pressure from traumatic changes by denying the existence or magnitude of these changes and this is acceptable for a short period of time; though, it is this time where they need help and support to give-up the unrealistic hopes and find the new but more realistic ones; patients in denial stage may spoil or suppress whatever behaviour changes attempted (Leydon et al. 2000).

9- Age:

There are many factors related to age that will affect patients physically and psychologically including: life style pattern, attitude, cognitive functioning, the presence of meaningful relationship and life accumulation of happy and unhappy events. Furthermore, there are common health problems among the elderly including gastrointestinal problems, cardiovascular diseases, and respiratory problems. In addition, elderly people may be fragile and less adaptive. This may affect patients' learning ability like cognition, the

degree they are willing to comply with treatment prescribed or change in their behaviour (Babcock et al. 1994).

10- Ethnicity:

The UK is an open country and hosts immigrants from all over the world which results in a community of diverse ethnicity with different cultural backgrounds. This may raise a few problems which need to be considered; for example in patients' values and beliefs about health and illness, religion, family relationship, nutritional habits, language barrier and communication patterns.

1.1.5.2 The health care provider:

The health care system can help patient's education by setting objectives, providing guidance, support, and performing continuous evaluation. This process is influenced by many factors including:

1. Health professionals:

Doctors consistently underestimated patients' desire for information (Gamble 1998). Clinicians need to be skilful in assessing patients' requirements for information and realistic about their ability to assimilate it. Doctors' communication skills are essential in the decision-making process; their behaviour during the consultation has a major role in reducing discrepancy between patients' preferred and perceived role in the decision-making process (Ford et al. 2003). Patients who perceived that their roles of involvement were matched to their preference for involvement in the decision- making process were more satisfied than patients who perceived that either they or their doctor had an exclusive control over the decision-making process (Gattellari et al. 2001). Surgeon's attitude has been identified by patients as an important factor in acquiring information during treatment;

being encouraged to ask questions, and giving realistic expectations and information about postoperative care (Harris 1998, Wolf 2004b).

Nurses have an important role in the care of cancer patients; they spend more time than any other member of the multidisciplinary team with patients, and consider patient education as part of their routine care. They also help in identifying and directing patients to quality health information sources (written, audio-visual or computer based) (Semple et al. 2002). However, despite the increasing use of specialist nurses and counsellors, the majority of patients prefer to hear the diagnosis from the hospital consultant (Meredith et al. 1996) as they consider doctors to be the main and trusted source of information, and nurses are recognised to be the main source for providing and clearing up additional information (Chumbley et al. 2002, Hope et al. 2000).

Gender differences in medical practice are real and can have a significant impact on the communication process and outcomes. Research to date indicates that women health care providers generally tend to conduct longer consultations, give more information, engage in more partnership conversation, are less directive, express more interest in psychosocial aspects of health (e.g. emotions, lifestyle, family), and are more openly reassuring and encouraging than male clinicians (Elderkin-Thompson et al. 1999, Roter et al. 1998, Street Jr 2002). Researchers in communicative behaviour realize gender difference but believe it is small in magnitude, and that male and female clinicians are generally more similar than different in their communication act (Roter et al. 1998); clinicians are likely to be more responsive to those patients who actively participate in the meeting and patients are likely to become more involved when their doctors are more patient-centred in their communication (Street Jr 2002).

2. Patient-doctor relationship:

Good patient-doctor relationship has a significant impact on the production of high quality of healthcare (van den Brink-Muinen 2002) and the professionals' role in the clinic is to establish a conducive environment for learning.

Doctor-patient relationships develop according to a complex interplay of style, perception and adaptation (Roter et al. 1997). The ability of the doctor to establish mutual understanding rests upon their ability to demonstrate a sympathetic attitude towards the patient such as showing understanding, paying attention, making eye contact with the patient and speaking in a pleasant voice; the patient's willingness to follow the doctor's directions can be achieved to motivate patients to foresee the outcome of treatment and its relevance to their lives. Also, the doctor needs to adjust to the patient's educational level, previous knowledge, cognitive function and life-situation (Stromberg 2002).

Patients' satisfaction with consultation is difficult to accurately measure; however, staff attention to psychosocial issues when providing medical treatment predicts patient satisfaction. Moreover, patient satisfaction with consultation was significantly influenced by the patient's age and psychological morbidity (Kindler et al. 2000, Shilling et al. 2003, Thomas et al. 1998, Walker et al. 2003). The doctor's social behaviour and attitude, including the affective quality of verbalisation made by both patient and physician, clearly predicted patient satisfaction (Ong et al. 1999). Other factors that may influence patients' satisfaction with clinical visits are not seeing the same doctor at each visit, waiting too long to see the doctor, and not being provided with enough time to discuss problems with the doctor (Grunfeld et al. 1999).

3. Health care system:

The patient education process is hampered by time limitations for teaching due to shorter hospital stay (bed shortages) and greater use of out-patient care settings. This factor is also aggravated by the shortage of numbers in professional staff which resulted in shorter out patient appointments to patients (Fallowfield et al. 1999).

4. Information sources:

The main form of information-giving is verbal during the consultation clinic or with the oncology nurse thereafter. Many patients do not retain much of the information given about their condition and its treatment in this manner (Fallowfield et al. 1999). Therefore, a majority of patients are provided with additional information from their cancer treatment centre. This can be in many forms but the most common one is in written format (Hope et al. 2000).

The role of well-designed, practical 'take-away' information material is to support the verbal consultation and continue the educational process outside the clinic (Thomas et al. 2000). Furthermore, the protective effect which preparatory information has on patients' psychological distress has been reported in randomized (Kerrigan et al. 1993, McHugh et al. 1995) and observational studies (Fallowfield et al. 1994) in a variety of medical conditions using a range of information materials (Thomas et al. 2000).

The target group for patients' education is people from different social classes, different background, different languages, different education levels and span over wide age range. This pool of people is vulnerable and amenable to education because of their illness. Therefore, the teaching agenda certainly needs to be comprehensive (but brief); and

cover diverse subjects with a degree of certainty and accuracy. Also, it needs to recognize that patient education can be provided by a large number of organizations and can take different forms at different places.

There are a wide variety of information sources used by cancer patients with positive outcomes. This includes family members, nurses, the internet, and independent charities for information and support (Hope et al. 2000, Jones et al. 2001, Leydon et al. 2000, McPherson et al. 2001, Stromberg 2002, Wolf 2004a). Information sources may be categorised into:

1) Population or large group targeted methods; these frequently use methods of mass communication like the media. The mass media sources include: hospital written information, books, magazines and newspapers, TV and radio, video and the internet (Bilodeau et al. 1996, Mills et al. 2000). The mass media may have little effect on individual behavioural change, but it has a large impact on the population level (cost effective); however, one of the major draw backs of mass media is that it is one-way communication. This means the users have little chance of stopping the presentation and/or asking questions to clarify difficulties they may encounter.

2) One-to-one or small group educational or counselling methods; these interpersonal sources include doctors, nurses, family and friends, voluntary organisations, support groups and professions allied to medicine (Nair et al. 2000). This form of intervention may significantly affect individual behaviour, but it has minimal impact on population (outcome-effective). The advantage of this form is that it is a two way communication. This means the individuals' understanding of the issues in question can be appraised and information provided customised to their level of knowledge. This form of

education can be personalised to the individual needs and any difficulties can be identified and worked through.

In a study of cancer patients, the consultant was the main source of information, followed by other health professionals (e.g. GP, oncology nurse...etc) parallel to family and friends. The internet, occupational therapists and patients support groups were the least frequently cited sources of information. Of particular interest in this study was the poor use of written information, TV/radio and support/voluntary groups by patients aged over 65 years (Mills et al. 2002). Public surveys at GP clinics in the UK on sources of information on cancer showed that people preferred the mass media methods. The sources were ranked in the order of books (39%), internet (36%), cancer charities (32%), magazines (18%) and others (10%). These results were influenced by the disease status, patients' gender and age. The study sample was non-cancer patients dominated by women (63% versus 37% for men) with a median age of 47 years (range 17-94) with mixed social classes. However, a careful look at the results revealed that people with a history of cancer in the family or relatives or friends and aged 65 years and above are likely to have same preference as cancer patients and rank the sources in the order of GP, books, cancer charity and last the internet (Adlard et al. 2003).

Criteria to be applied to patient education materials are related to accuracy, content, objectives, currency, point of view, scope of coverage, organisation, style and format and audience level (Dalton et al. 1981). There is a detailed description and guidelines for the production and advantages of different educational materials in The POPPi Guide (Duman et al. 2000) and the client education (Babcock et al. 1994).

Many information sources are criticised for being written in a language too difficult for patients to understand, for its high readability level to the public, for not addressing patients' needs adequately, for its poor design, received too late for use and for reflecting the professionals' views only (Coulter et al. 1998). Additionally, there is a wide gap in research for the efficacy of these methods in long term retention of knowledge gained and its ability to change patient's behaviour. Because of the lack of main aims and description of educational intervention used in clinical trials, researcher's could not measure the efficacy of each method nor the consistency between different sources (Lauver et al. 2002, Meredith et al. 1996, Semple et al. 2002). Furthermore, because the patient has access to many different sources, there is a dilemma about when it is appropriate to give specific information to patient (Entwistle et al. 1998).

1.2 Aims and objectives of the study

By the end of this study we aim to achieve the followings:

- Survey patients' satisfaction with information provided at the maxillofacial unit and the oral medicine clinic and illicit area of deficiencies; and factors may contribute to differences between patient groups.
- Verify patient's demand for additional information and from whom.
- Find out patient's preferred format of additional information
- Identify the best source of information for patients
- Report any correlations between the patients' demographics and their information level as well as the preferred format of additional information.

1.3 Material and methods

The study will survey the information delivery system in two different places the oral medicine clinic and the maxillofacial surgery clinic. Thus, postoperative oral and pharyngeal cancer patients from the Maxillofacial Unit and pre-cancer and non-cancer patients on regular follow-up in the Oral Medicine Unit were recruited to the study. A self administered survey questionnaire was used for this purpose (Appendix 1).

1.3.1 Standard applied:

- The maxillofacial unit: The unit was providing services described in the NICE guidance on commissioning cancer services (2004) Improving outcomes in Head and Neck cancer manual. Information provided to patients informally through the multidisciplinary team; the team is made-up of a maxillofacial oncology surgeon, an oncologist, a dietician, a speech therapist, a clinical nurse specialist and one/two senior house officers. A prosthodontist has a clinic in the Unit to complement the dental treatment for the cancer patients and can be consulted when needed. A liaison psychiatrist is also available in the dental hospital. Patients included were postoperative oral and pharyngeal cancer patients who have gone through the experience of cancer diagnosis and treatment and in the rehabilitation phase.

Education for the patients (including the families) is the main form of psychosocial support provided in the unit as part of routine patient care, and patients offered information to improve compliance, to reduce anxiety, promote self-care and development of appropriate coping strategies. This can be in the form of providing leaflets on the racks in the waiting area from voluntary cancer organisations plus a locally produced handout describing briefly the procedures patients need to follow during the course of treatment and include the

important contacts (names and phone numbers) in the Unit that the patients might need. A support group is organised once a month by the oncology nurse at the Unit with voluntary attendance, although patients are encouraged to attend. This group aim to provide peer support diminishes feelings of isolation, which may facilitate the sharing of information and experience and reinforce active coping strategies.

This approach has been described before (Clark 2000) and the oncology nurse is central in organising this support, although the process is delivered by all members of the multidisciplinary team with the aim of improving the treatment outcome.

Newly referred patients are routinely seen within a maximum period of two weeks from referral and if diagnosed with cancer, preparation for surgery will take approximately 3-4 weeks. Postoperative care and the risk of recurrence demand that patients are reviewed once every week for the first month, once every two weeks for the next three months, once a month for the 1st year, every 2-3 months for the 2nd year and every 3-6 months up to the 5th year. Some patients will start adjuvant radiotherapy treatment after surgery then will resume follow-ups after completion of the radiotherapy course. The Unit is located in the Camden and Islington area for central London. Patients in this area are very diverse in education levels, ethnic background and socioeconomic status.

- The Oral Medicine clinic: Pre-cancer and Non-cancer patients were recruited from patients attending the Oral Medicine Unit at the Eastman Dental Institute for Oral Health Care Sciences, University College London. Pre-cancer patients are patients have been diagnosed with known precancerous mouth conditions (mucosal mainly) such as epithelial dysplasia and lichen plants. Non-cancer patients are patients have been diagnosed with known chronic mouth diseases or condition (mucosal mainly) such as Recurrent Aphthus

Stomatitis or Sjogrens disease; it is important that the disease does not carry an increased risk of malignant transformation. Information provided by the consultant or one of his specialist registrars. The department policy is to give patients information sheet after verbal explanation of their newly diagnosed disease and re-enforce this at subsequent appointment. A general information booklet about the direction and services provided by the Eastman Dental Hospital is also available at the information help desk. Patient's comments regarding the level of services they receive are invited by cards to be filled in and placed in a box at reception.

Patients are seen and treated within two weeks of referral; also, patients are kept on regular review appointments depending on the severity of the disease signs and symptoms. As a teaching hospital, patients expect also to see postgraduate dental students, medical undergraduate and nurse students. The Eastman Dental hospital is also in the Camden and Islington area for central London and it is a tertiary referral hospital, so patients can be very different in their characteristics.

The exclusion criteria were kept to a minimum and only people who had major limitations such as (couldn't speak or understand English, or were physically or mentally challenged) were excluded. This is in order to have a representative sample and avoid selection bias as much as possible. Also, newly referred patients were not given the option to participate. During the two month period of the study 120 patients approached but only 116 patients were recruited from the three groups.

1.3.2 The survey questionnaire

The survey instrument was self-administered questionnaire. The design and content of the questionnaire were made according to the following steps, the process has been described by L. Frazer and M. Lawley (Frazer et al. 2000):

- The required information was determined (table 1.3.2.1) and the sample of the study was decided to be oral cancer and oral medicine patients (pre cancer and non-cancer).

- The interview method was decided to be self administered questionnaire and to be completed in the clinic while patients waiting to see their doctors. Therefore, it was decided that the questionnaire should not take more than 10 min. to complete.

- A draft questionnaire was prepared, careful attention was paid to the content and words of the questions, also to the response format and layout. The questions were made to be fairly general and comprehensive. This may reduce the sensitivity of the questions but ensured that it was suitable for different types of patients. Moreover, the questions were made to be self explanatory as much as possible, the wordings were made to be clear and simple, in a kind and personalised manner. The Eastman logo was placed on the cover page so that patients could clearly identify the organisation sponsoring the study.

- The design of the questionnaire and its outlay was surveyed and revised by the researcher and oral medicine consultant, patients were involved as well.

- Upon piloting the questionnaire on a few patients, few changes were made. The questionnaire designed to have Yes/No responses in sections A & B, but in order to

reduce the numbers of non-responses (blank) the option of (Not sure) answer was added and considered at the end as No answer. The number of questions reduced to 10 items in section A and 4 items in section B. There were some changes in the wordings of some questions.

- The final draft produced and applied (see appendix I).

Table 1.3.2.1Contents of the patients' knowledge survey questionnaire

	No. of items	Subject examined
Section A	10 items	patients' awareness of their overall management
Section B	4 items	patients' understanding of their treatment plan
Section C	4 options	patients' rating for sources of information about their disease
Section D	4 options	patients' desire for more information (yes/no) and from whom
Section E	5 formats	patients' ranking of forms they prefer to see additional information in

1.3.3 The design of the study and implementation

This is a cross sectional survey study where patients completed the questionnaire once. This type of studies focuses mainly on three goals:

1. to describe the characteristics of a population
2. to describe the differences between the people in the population
3. to describe the correlations of patients' characteristics to the questionnaire scores.

Patients' recruitment was limited to one day per week from each clinic as the multidisciplinary oncology clinic is running once a week and the oral medicine unit was limited to one consultant clinic once a week. The study was explained to both consultants involved and the two receptionists and nurses in both units in case patients enquired about the study.

The researcher approached the patients in the waiting area before they entered the surgery to explain the aims of the study. After brief introduction, patients were verbally consented and asked to complete the questionnaire and hand it over to the receptionist before they leave the clinic. There were no interferences from the researcher or the receptionist during the process of answering the questionnaire as the wording and questions were simple and self explanatory. This was intended to minimise bias response between patients.

The intention was to include all patients attending the clinics during the recruitment period, however, there was occasional filtering-out for patients whom the researcher felt they were too unwell or too depressed to answer the questionnaire. Also there was some random exclusion of eligible patients when clinics workloads were very heavy. One cancer patients refused to participate due to traumatic memories.

1.3.4 Scoring and Statistical analysis

The patients' answers were collected from the questionnaires with their demographics and diagnosis data taken from the departments computers or patients case notes. The combined data was tabulated in a statistics programme-SPSS (Statistical Programme for Social Science) version 11. At the end of data collection, the data was

revised and cleaned of repetition and discrepancies in the responses and a recoding procedure was carried out for some variables for further analysis.

For section (A) and (B), patients who left more than 50% of the items (5 items for Sec-A, 2 items for Sec-B) were excluded. These procedures will validate the responses and help to filter out patients who probably didn't understand the questions or were not interested in answering the questions; patients who were excluded by this method were counted as missing. The categorical answer (yes and no) for questions in these two sections were recoded into numerical value of 1 and 0 respectively. The yes answers were further transformed to percentages of the number of questions in the section (i.e. yes = 10% in Sec-A, and yes = 25% in Sec-B).

For computing the final score in sections A & B for each patient, there was the problem of missing answers. As the intention was to know how well patients were informed the final (yes) answers was calculated as a percentage from the total items/questions in the section, and the (no) answers and missing answers were considered together.

In section C, patients needed to answer at least 2 out of 4 options for their answer to be included in the analysis. Section D was in two parts (do patients want more information and if yes, from whom); it is expected that only those who answered Yes would further choose from whom. In both sections the results were presented as a percentage of the patients answers.

Section E was a Likert scale where patients ranked the different sources of information listed from 1 (most preferred) - 5 (least preferred). Patients needed only to make at least two choices in order to have their answers included in the analyses because

some patients were not able to rank some sources due to the lack of previous experience of the method as a source for information.

Patients were asked to complete the questionnaire before they see the doctors as their responses could be influenced by their feelings about the consultation that day after the consultation.

Descriptions of the participants involved in the study are summarized in tables by using percentages, means, standard deviation, confidence intervals (95%) and box & whisker plots (25^{th} and 75^{th} centiles and range) where appropriate. For testing the null hypothesis, parametric and non-parametric tests will be used where appropriate. Correlations will be tested by the Pearson Chi square test for correlation and scatter plots.

1.4 Results

Over a period of two months 116 patients were recruited from the three groups. Ten patients out of the 116 patients were excluded due to the inability to acquire a clear diagnosis from their case notes. The sample was 106 patients divided into three groups; 35 oral cancer patients, 34 pre-cancer patients and 37 non-cancer patients.

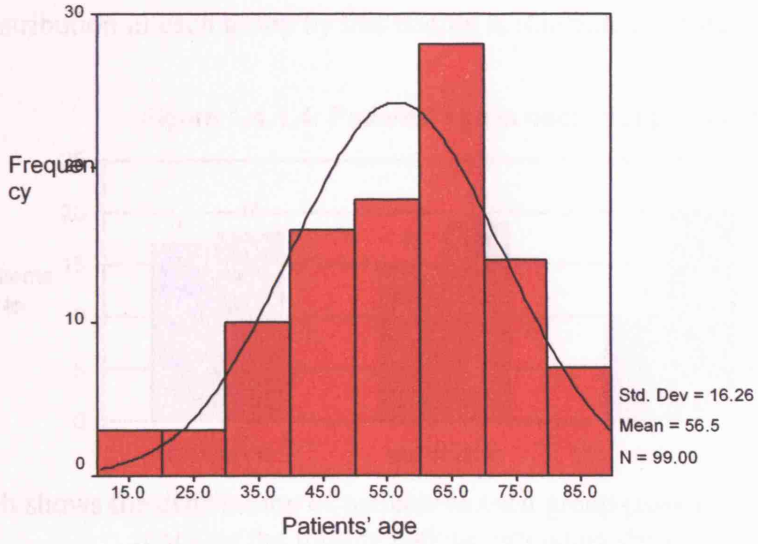
1.4.1 Patients characteristics

Patients' distribution by gender, marital status and diagnosis are summarised in figure 1.4.1.1. The median age of the patients is 59 years (range 16-88) with symmetrical distribution around a mean age of 56.5 years (figure 1.4.1.2).

Figure 1.4.1.1: Summary of patients' demographics

The graph shows a similar distribution of patients' number according to their gender, marital status and disease group.

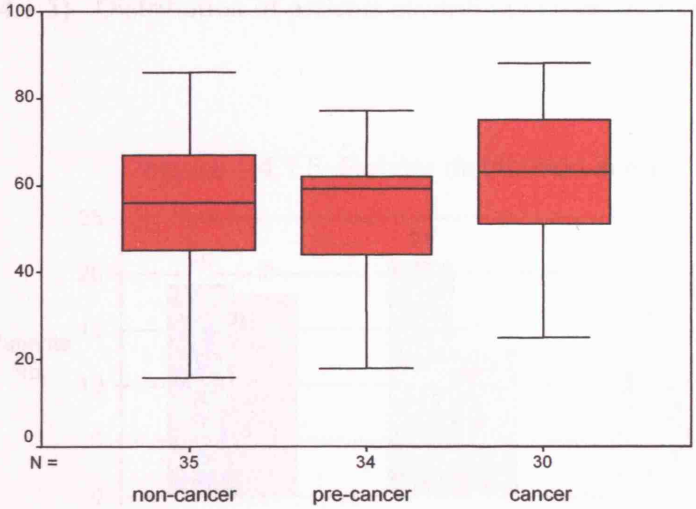
Figure 1.4.1.2: Age distribution for all patients



The graph shows a normal distribution of patients' age around a mean age of 56 years for all the patients included in the study.

The mean age in non-cancer patients was 55 (SD 17.3) with a median age of 56 years; the pre-cancer patients was 54.7 (SD 13.4) with a median age of 59 years; and in the cancer patients it was 60.3 (SD 17.8) with a median age of 63 years (figure 1.4.1.3).

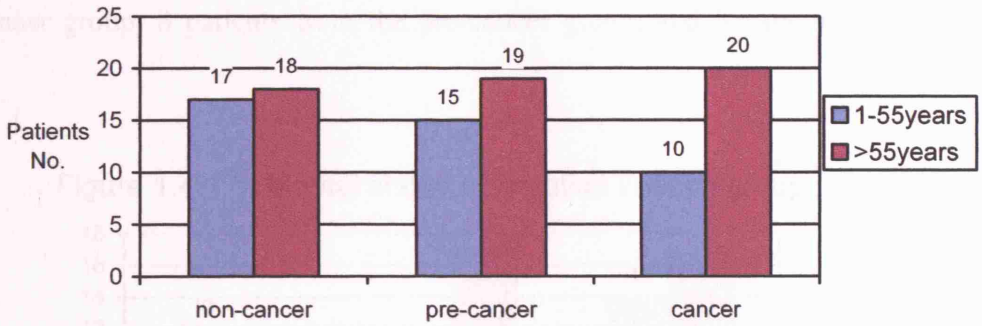
Figure 1.4.1.3: Age distribution in each group



The graph shows the age range and median age for the patients in individual group

For analysis purposes patients age were coded into 1-55 years and >55 years, the patient distribution in each group by this coding is illustrated in figure 1.4.1.4.

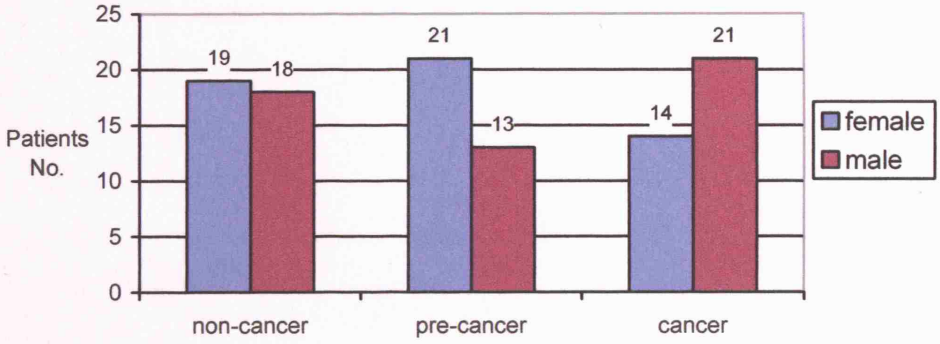
Figure 1.4.1.4: Patients' age in each group (coded)



The graph shows the distribution of patients in each group (based on their age code) which replicate the routine patients attending these clinics.

The male/female distribution according to the disease groups was even in the non-cancer group; however, there were a higher number of females in the pre-cancer group, probably as patients diagnosed with Lichen Planus (L.P.) are common in the oral medicine clinic and L.P. is predominant in females. There were a higher number of males in the cancer group. This data reflects a normal distribution of patients attending these clinics (figure 1.4.1.5). Distribution of patients according to their marital status is shown in (figure 1.4.1.6).

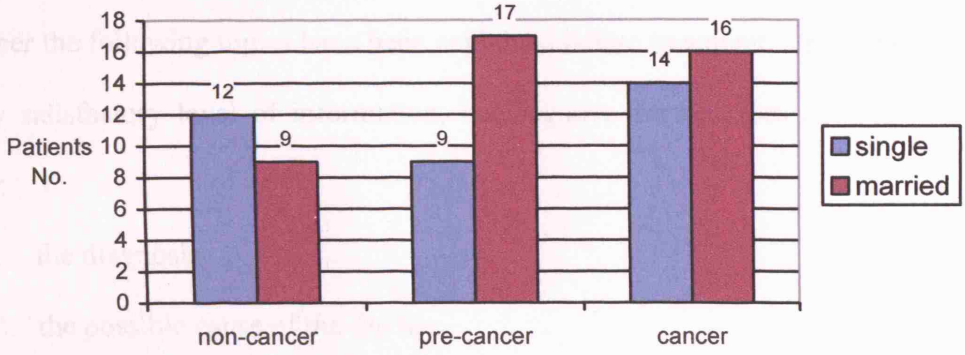
Figure 1.4.1.5: Gender distribution in each group



The graph above shows more male patients in the cancer group as oral cancer is more common in males than females. Pre-cancer group has more female patients as this could be due to the high frequency of patients with Lichen planus in the oral medicine clinic.

The variable marital status was viewed under two categories; married which include married patients and patients with partner; single which include single, divorced and widowed patients. There were 29 patients with missing marital status, 16 patients from the non-cancer group, 8 patients from the pre-cancer group, and 5 patients from the cancer group.

Figure 1.4.1.6: Marital status distribution in each group



The graph above shows a similar distribution of patients in each group (based on marital status) but more married patients in the pre-cancer group as there were more female patients in this group.

1.4.2 Overall management (section-A):

This section aimed to examine the hypothesis that all patients would have a satisfactory information level about their disease and its management. Out of the 106 patients included in this study 6 patients failed to answer at least 50% of the items and were excluded (see scoring procedure page 103). Therefore, the final sample size for this section was 100 patients (94%). The questions ask the patients to state (yes / no / not sure) as to whether the following topics have been explained before treatment; a positive answer could imply satisfactory level of information, but negative answer does not imply a need for more:

1. the diagnosis
2. the possible cause of the disease
3. the kind of investigation he/she needs
4. the treatment required
5. who is going to treat him/her
6. where is he/she going to be treated
7. the possible complication of treatment
8. the likely outcome of treatment
9. the effect of the disease or treatment of his/her emotion
10. details of patients support groups

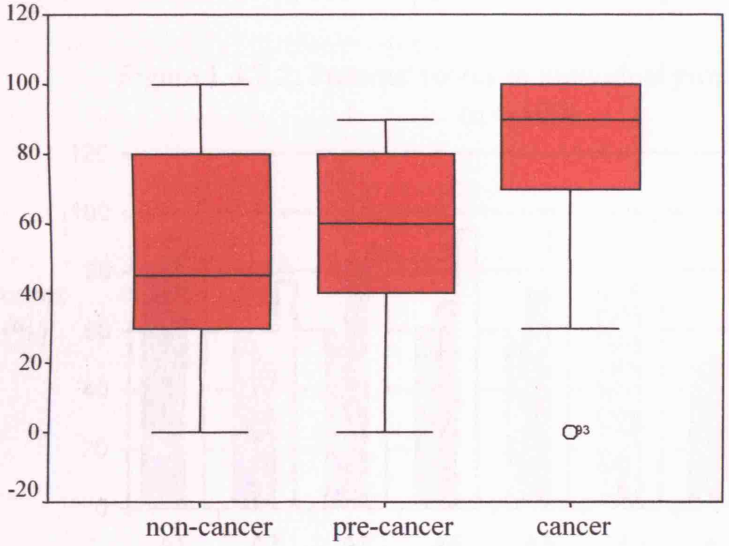
A summary of the patients' scores for these questions is presented in table 1.4.2.1. It is noteworthy that the "not sure" answer considered as "no" answer in the final analysis. The patients' level of information (Yes answer) varied in each group; the pre-cancer and non-cancer group had a comparable mean score but the median score was higher in the pre-

cancer patients. The cancer group of patients has a higher mean score and higher median score (figure 1.4.2.1).

Table 1.4.2.1: Summary of patients' scores in section-A (total of 100 patients)

	N	Mean (SD)	Median
Non cancer patients	34	49.7 (32.6)	45
Pre-cancer patients	33	54.9 (26.4)	60
Cancer patients	33	82.1 (24.8)	90

Figure 1.4.2.1: Differences in patients' scores in Sec-A (n = 100)

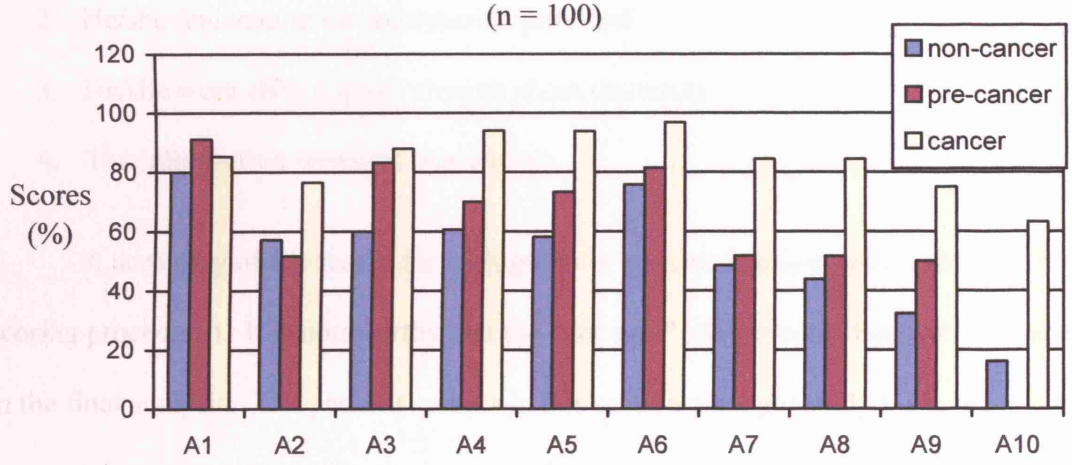


The chart illustrates the significant difference in the scores for Q-A between the cancer patients and the non-cancer and pre-cancer patients

To test for a significant difference between the three groups the Kruskal Wallis test applied. The test failed to support the hypothesis (χ^2 (2) = 25.806; p = 0.000); this implies the existence of a significant difference between the three groups. The Mann Whitney test was a suitable test for locating the significant difference between the three groups. There was a significant difference between the median score for the cancer patients and the median score of the non-cancer patients (Z = -4.42; p = 0.00); and the median score of the pre-cancer patients (Z = -4.36; p = 0.00). However, the difference between the median score for non-cancer and pre-cancer was not significant (Z = -.67; p = 0.499).

A more detailed look as to how patients in the three groups answered this section (figure 1.4.2.2) reveals that there is a small dip in the three groups at item A2 (possible cause of the disease) and a gradual decline in the last four items concerning the possible treatment complications, prognosis, emotional effect of disease and support groups respectively. Also, almost 50% of the pre-cancer and non-cancer patients did not know about the complications of treatment (A7) or the likely prognosis of their disease (A8) or the effect of the disease on their psychology (A9). Support groups are mainly for cancer patients, so non-cancer or pre-cancer patients are not expected to know much about it.

Figure 1.4.2.2: Patients' scores in individual group for section-A
(n = 100)



The chart demonstrate patients' scores (Yes answers) of knowledge about their disease (A1), possible causes of disease (A2), the investigation they need (A3), the treatment required (A4), the person on charge of the treatment (A5), the places for treatment (A6), the possible complications of treatment (A7), the prognosis (A8), the psychological side effects of treatment (A9) and awareness about patients support groups (A10). The chart highlights the inferior scores for the non-cancer and the pre-cancer patients especially in items A2, A7, A8, A9, and A10 compared to the cancer group

For the correlation of the patients' characteristics and their scores for each group, the Pearson correlation test was applied and found to be not significant for association of patients' scores with patients' age, gender and marital status.

1.4.3 Treatment plan (Section-B):

This section aimed to examine the hypothesis that all patients have equal amount of information about their treatment plan. Out of the 106 patients included in the study; 9 of them answered less than 2 items and were excluded. Therefore, the final sample size was 97 patients (91.5%). The section examined patients' knowledge about the treatment plan; patients were asked to answer (yes / no / not sure) to the questions asked in the following subjects (a positive answer could mean a satisfactory level of knowledge, but negative answer does not mean dissatisfaction):

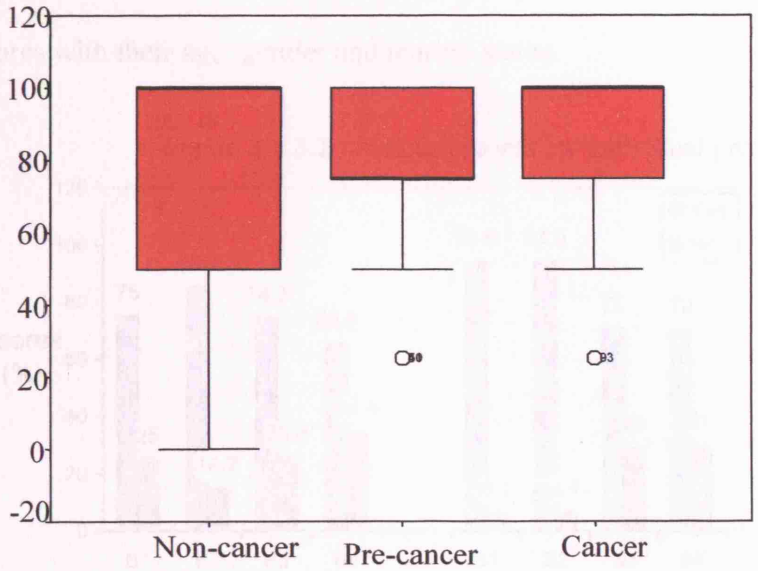
1. Given enough information on possible treatment choices
2. He/she understand the information provided
3. He/she were able to make choices about treatment
4. The information provided was correct

A summary of the scores for each group of patients is presented in table 1.4.3.1 (see scoring procedure). It is noteworthy that the "not sure" answer considered as "no" answer in the final analysis. The patients' scores in this section were generally high; the mean scores were comparable in the pre-cancer and cancer patients, however, the median score for cancer patients was 100%, while the median score for non-cancer patients was 75%. The non-cancer patients had a better median score than the pre-cancer patients (100%), but a much wider range (figure 1.4.3.1).

Table 1.4.3.1: Summary of patients' scores in Sec-B (total of 97 patients)

	N	Mean (SD)	Median
Non-cancer	32	74.22 (35.6)	100
Pre-cancer	33	79.55 (22.9)	75
Cancer	32	87.5 (17.96)	100

Figure 1.4.3.1: Difference in patients' scores in Sec-B (total of 97 patients)



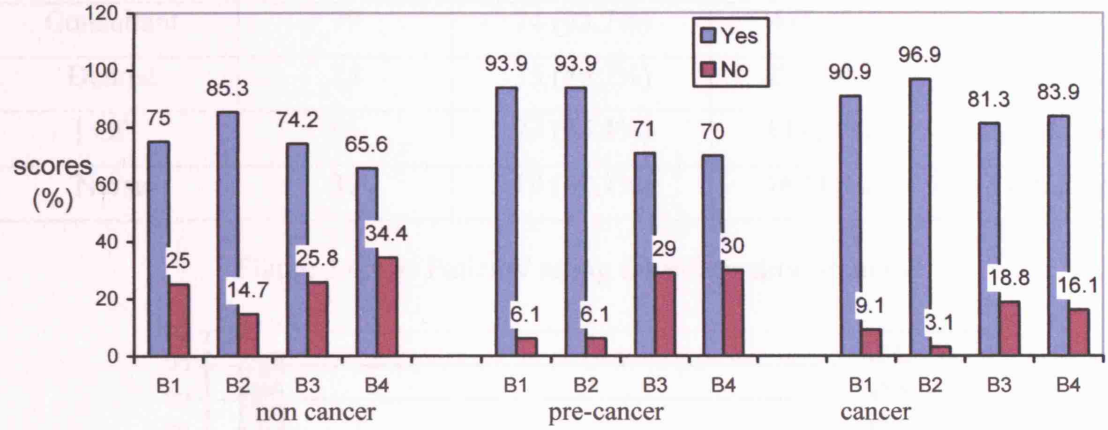
The graph shows that there is no difference in knowledge about treatment plan between the three groups

The Kruskal Wallis test failed to reject the hypothesis (χ^2 (2) = 1.97; p = 0.37); this implies that there are no significant differences in knowledge about treatment plan between the cancer, pre-cancer and non-cancer patients.

Figure 1.4.3.2 demonstrates the patients' answers in section -B for each group. The cancer and pre-cancer patients scores adequately high (>90%) in items B1&B2, this indicates that patients had adequate information on the choices of treatment and that the information provided was well understood. Non-cancer patients scored relatively well in these two items, but 25% felt they needed more information on other treatment choices. The positive attitude on the ability to make choices about the treatment plan (B3) was shared by 70-80% of the patients. However, the patients' perception on the outcome of treatment received varied (B4). Eighty four percent of the cancer patients thought they had results similar to what they were told during the treatment plan process; this percentage dropped to 70% in the pre-cancer patients and alarmingly to 65% in the non-cancer

patients. The Pearson correlation test was not significant for correlation of the patients' scores with their age, gender and marital status.

Figure 1.4.3.2 : Patients' scores for individual group for Sec-B



The chart demonstrate patients' scores (Yes answers) of knowledge about possible treatment choices (B1), clearness of information provided (B2), ability to make choices if treatment (B3) and the virtue of information provided (B4). The chart shows a relatively high percentage of patients that were not able to make choices about their treatment (B3) nor were they adequately informed about the outcome (B4)

1.4.4 Source of information (Section C):

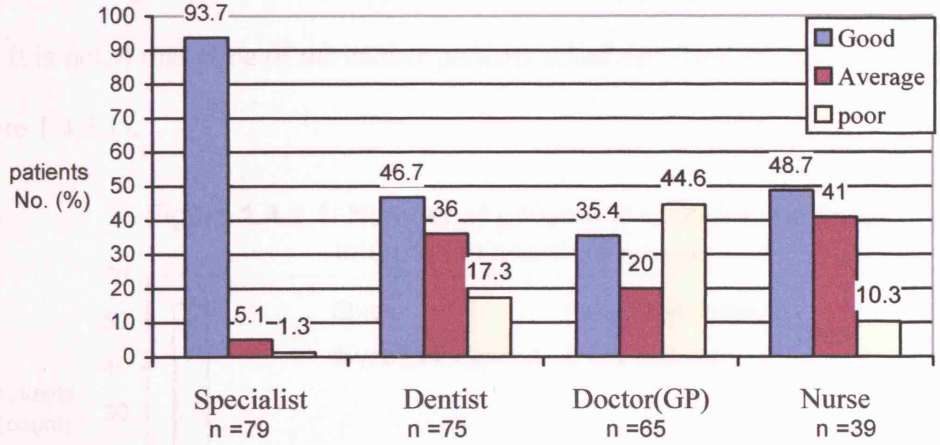
In this section, the patients were asked to rate different sources of information. Out of the 106 patients included in the study, 23 patients were excluded as they rated less than 2 of the sources listed. Therefore, the total number of patients included in the analysis was 83 patients (78.3%).

Patients were expected to rate the 4 sources for information listed in this section, the consultant, the dentist, the general practitioner (GP), and the nurse for efficiency in providing information (1= best, 2 = average, 3 = poor). It was acceptable to rate at least 2 sources as some patients may not have experience with all the 4 sources, and this may change the number of patients rated each source. Therefore, the scores for each source were calculated in percentages from the number of patients rated the source (table 1.4.4.1).

Table 1.4.4.1: Patients' rating of information sources in Sec-C

	No. of patients involved	Good	Average	Poor
Consultant	79	74 (93.7%)	4 (5.1%)	1 (1.3%)
Dentist	75	35 (46.7%)	27 (36%)	13 (17.3%)
GP	65	23 (35.4%)	13 (20%)	29 (44.6%)
Nurse	39	19 (48.7%)	16 (41%)	4 (10.3%)

Figure 1.4.4.1: Patients' rating for information sources



The chart showed that patients ranked the specialist as the best source of information and highlights the high percentage of patients rated the GP as poor source of information

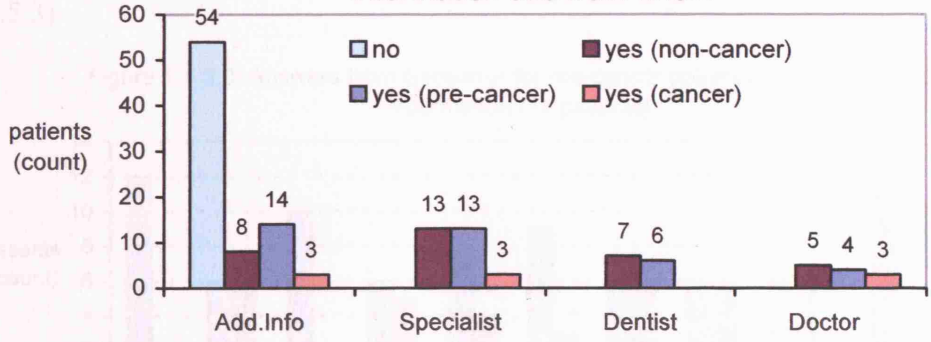
As demonstrated in figure 1.4.4.1, the patients ranked the consultant (specialist) as the best source for information. Dentists were considered to be in the second place as most of the patients had diseases related to their mouth. Disturbingly is the high "poor" score for the GP being a source for information related to mouth disease. The nurse scores are probably better than the dentist scores, although this may reflect the oral cancer patients' opinion only, as 80% of the patients involved were from the cancer group.

1.4.5 Patients need for more information (Section D):

Section D, was two parts: the first part asks patients if they wish for more information (Yes / No) and the second part is to name the source for that information (the

consultant, the dentist, the GP). Out of the 106 patients included in the study, 79 patients (75%) answered this section and 25 of them (31.6%) asked for more information. The distribution of patients that requested more information was 8 non-cancer patients (32%), 14 pre-cancer patients (56%) and 3 cancer patients (12%). Twenty seven (27) patients did not answer this section; this can be due to the outlay of the question. Assuming that patients who asked for more information (25 patients) will continue and choose the source the result showed that almost all the patients listed the consultant (except one patient from the pre-cancer group), 13 patients (52%) chose the dentist, and 12 patients (48%) chose the GP. It is noted that none of the cancer patients asked for more information from the dentist (figure 1.4.5.1).

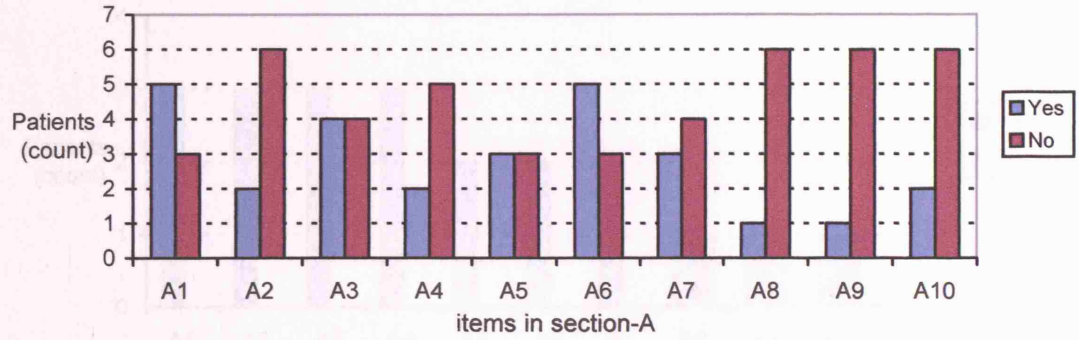
Figure 1.4.5.1: Number of patients who desire additional information and from whom



The graph shows that the majority of patients do not want more information and those who asked for chose mainly the specialist (consultant).

The free text part of the question was omitted because only 3 patients wrote their comments and it is thought not representative for the 25 patients asked for more information. In the event it was decided to examine those patients who asked for more information by analysing further their answers is section-A (the overall disease management) in attempt to find out the topics patients may need to know more about. In the non-cancer group (8 patients) there was a large number of patients who negatively answered many items in Sec-A especially items 2, 4, 7, 8, 9 and 10 (figure 1.4.5.2).

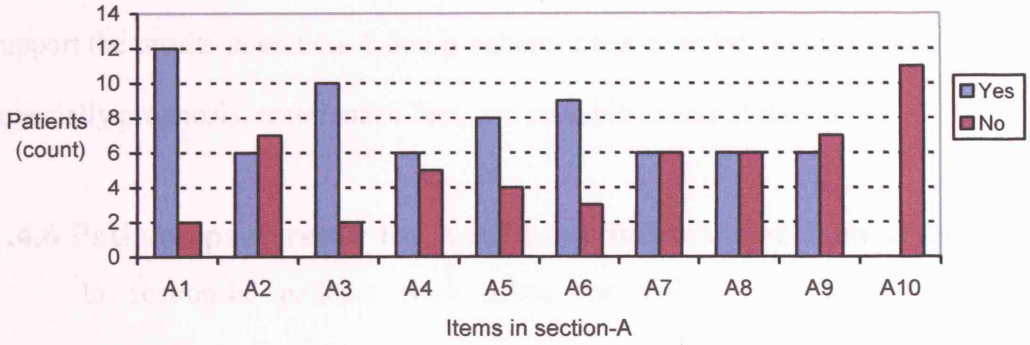
Figure 1.4.5.2: Answers from section-A for non-cancer patients who wish for more information (8 patients)



The graph shows patients' answers for items in the overall management section:(A1) knowledge about the disease, (A2) possible causes of disease, (A3) the investigation they need, (A4) the treatment required, (A5) the person on charge of the treatment, (A6) the places for treatment, (A7) the possible complications of treatment, (A8) the prognosis, (A9) the psychological side effects of treatment and (A10) awareness about patients support groups. Negative answers may indicate the area where patients need more information.

In the pre-cancer group (14 patients), although the negative responses are present in most of the items, the response is high in almost the same item of 2, 7, 8, 9, and 10 (figure 1.4.5.3).

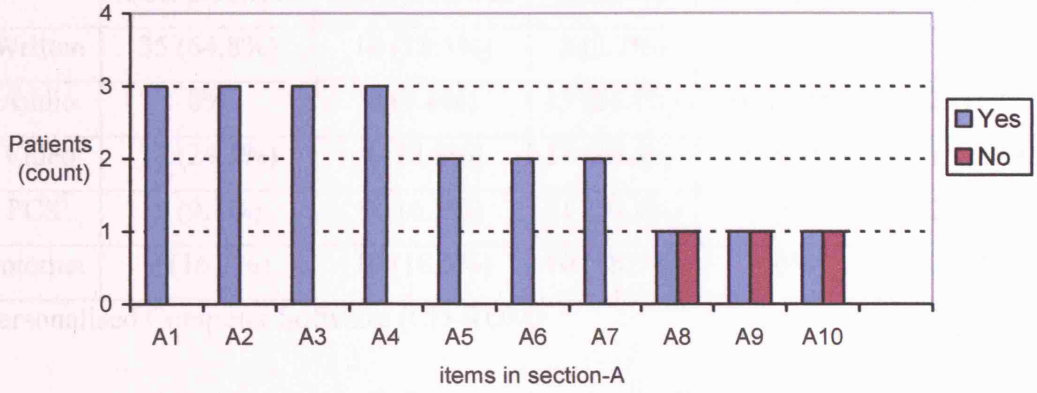
Figure 1.4.5.3: Answers from Section-A for pre-cancer patients who wish for more information (14 patients)



The graph shows patients' answers for items in the overall management section:(A1) knowledge about the disease, (A2) possible causes of disease, (A3) the investigation they need, (A4) the treatment required, (A5) the person on charge of the treatment, (A6) the places for treatment, (A7) the possible complications of treatment, (A8) the prognosis, (A9) the psychological side effects of treatment and (A10) awareness about patients support groups. Negative answers may indicate the area where patients need more information.

In the cancer group, the number of patients who wish for more information was very small (3 patients) and possibly they need more information in the last three items 8, 9, and10 (figure 1.4.5.4).

Figure 1.4.5.4: Answers from section-A for cancer patients who wish for more information (3 patients)



The graph shows patients' answers for items in the overall management section:(A1) knowledge about the disease, (A2) possible causes of disease, (A3) the investigation they need, (A4) the treatment required, (A5) the person on charge of the treatment, (A6) the places for treatment, (A7) the possible complications of treatment, (A8) the prognosis, (A9) the psychological side effects of treatment and (A10) awareness about patients support groups. Negative answers may indicate the area where patients need more information.

Although, patients receive different kind of information because of their disease status, the patients negative answers in the overall management (section-A) are promising areas where patients may need more information. Nonetheless, the results from this section support the results in section-A that is patients need more information about various aspects especially prognosis, emotional effect, and possible causes of the disease.

1.4.6 Patients preference for Additional information format (Section-E)

In section-E; patients were asked for their preferred format of additional information material. Patients were asked to rank 5 formats: written; audio; video; personalised computer software (PCS) and the internet (1= most preferred to 5 = least preferred).

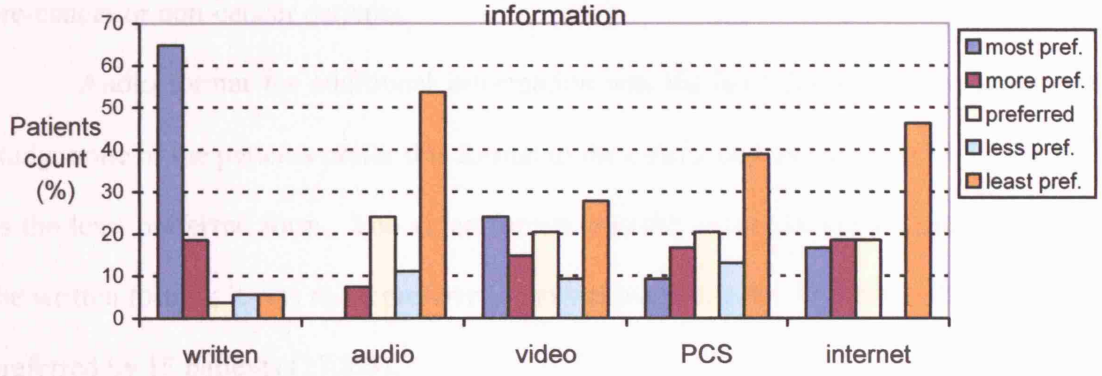
Out of the 106 patients, 52 patients rated less than two formats and were excluded. Therefore, the sample size for this question was only 54 patients (51%). The results are displayed in percentages of 54 patients (table 1.4.6.1) and are illustrated in figure 1.4.6.1.

Table 1.4.6.1: Patients' preferences for forms of additional information in Sec-E (n = 54)

	Most preferred	more preferred	preferred	less preferred	least preferred
Written	35 (64.8%)	10 (18.5%)	2 (3.7%)	3 (5.6%)	3 (5.6%)
Audio	0%	4 (7.4%)	13 (24.1%)	6 (11.1%)	29 (53.7%)
Video	13 (24.1%)	8 (14.8%)	11 (20.4%)	5 (9.3%)	15 (27.8%)
PCS†	5 (9.3%)	9 (16.7%)	11 (20.4%)	7 (13%)	21 (38.9%)
Internet	9 (16.7%)	10 (18.5%)	10 (18.5%)	0%	25 (46.3%)

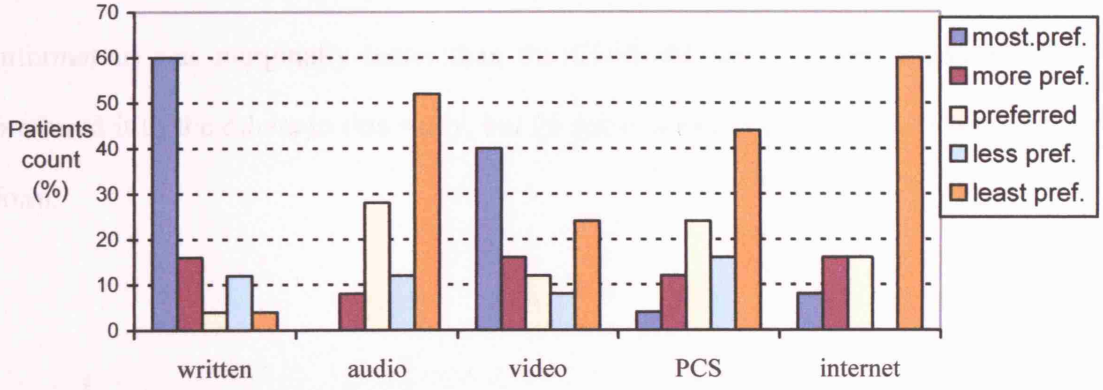
† Personalised Computer Software (CD-ROM)

Figure 1.4.6.1: Patients' preference for forms of additional information



This graph shows that written format was the most preferred form for additional information by all the patients.

Figure 1.4.6.2: Oral cancer patients preference for forms of additional information



This graph shows that oral and pharyngeal cancer patients have a similar preference of information format as the general group of patients.

As indicated in graph 1.4.6.1, the written format is the most preferred form followed by the video tape and the least form was the audio tape. The oral cancer patient group (25 patients) produced similar results also (figure 1.4.6.2).

The written format was the first choice for 35 patients (64%) and only 3 patients did not prefer it (5.6%). There was no significant association between this format with patients' age, gender, marital status or disease type. This implies that it is preferred by both male and female patients, old and young patients, single and married patients, and cancer or pre-cancer or non-cancer patients.

Audio format for additional information was the least favoured by cohorts in this study; none of the patients prefer this format to the others, and 29 patients (53.7%) ranked it as the least preferred form. The video format was the second in order of preference after the written format; it was more preferred than written format by 13 patients (24%) and least preferred by 15 patients (27.8%).

Personalised information supplied in a CD-ROM format was of concern in this study. Only 5 patients (9.3%) preferred this format to the others, compared to 21 patients (38.9%) who rank it the least preferred form. The internet method for supplying additional information was marginally better than the CD-ROM format where 9 patients (16.7%) preferred it to the others in this study, but 25 patients (46.3%) ranked it the least preferred form.

1.5 Discussion

This study was designed as a cross sectional study which examined patients' attitude and characteristics to enable assumptions to be made and a correlation analysis completed. Self completed questionnaire surveys have the advantage of being completed quickly and avoid the problem of interviewer bias; however, they have a serious problem of response bias.

In this study, the intention was to have a stratified random probability sampling (patients have an equal chance of being included in each group of the sample) by random selection from the computer list of patients attending the clinic during the research period. This method is superior in ensuring that the selected sample represents the population. In the event a non-probability accidental sampling was adopted for the following reasons:

1. There was a time limit factor for the study.

2. The sampling relied on the patient's availability, willingness to answer the questionnaire and how busy the clinic was on that day.

These factors and the presence of exclusion criteria introduced a response bias to the results (i.e. the population of patients visiting the oral medicine or the oral oncology clinic is not fully represented in this study sample). However, the patients' selection criteria were broad in an attempt to have a more representative sample of patients. Also, patients' characteristics and representation were comparable to the non-cancer and pre-cancer patients routinely treated in oral medicine and oral cancer patients treated in the maxillofacial unit.

The questionnaire was designed for specific aims in this study and the participation of 116 patients out of the 120 patients approached (96%) indicated that the questionnaire was well received by the patients; nonetheless, the questionnaire psychometric property is not tested, and the questionnaire may needs further changes.

1.5.1 Knowledge of disease management and treatment plan

The response rate was high in both Section-A and Section-B of the questionnaire (94% and 91.5% respectively). Patients generally said they were relatively well informed about their management as outlined in the study questionnaire and their treatment plan. Oral cancer patients were significantly better informed ($p<0.001$) than the non-cancer or pre-cancer patients about the general management of their disease (section 1.4.2). In the treatment plan, oral cancer patients had a higher score than pre-cancer and non-cancer patients (mean scores: 89, 79, 74 respectively); however, this difference (in median score) was not statistically significant (section 1.4.3).

Oral and pharyngeal cancer patients are managed in the maxillofacial unit by a multidisciplinary team (MDT) that coincide with the NICE guidelines for the care of head and neck cancer patients. The team is made-up of health professionals with experience in management of oral and pharyngeal cancer patients, with an aim to maximise treatment outcome, including information and support. Therefore, patients receive information from multiple sources and in different settings and time. More importantly is the prominent role of the specialist clinical nurse (part of the MDT) in providing information and support to patients, which was highlighted in the fact that 80% of the patients who rated the nurse as good source of information were oral cancer patients.

In the literature, many factors have been reported to help increase patients satisfaction with the information provided, including having more than one source of information (Wolf 2004a), individualisation of information, more time during consultation, repetition of information, the choice to have a second opinion, an honest and kind surgeon attitude that encourages patients to participate in the decision-making process, a continuous supply of information as and when needed and continuation of care after treatment (Newell et al. 2004, Wolf 2004b). Most of these factors are adopted in the care delivery system at the unit, and this is shown to be successful in satisfying oral and pharyngeal cancer patients' needs for information, as they have a mean score of 82% (median is 90%) in the overall management question and 88% in the treatment plan question (median is 100%). Also, the psychosocial support element provided by nurses is a significant difference in the care of cancer patients from what is provided for oral medicine patients; and it is difficult to separate patient's satisfaction with information from satisfaction with psychosocial support received. Another important contributing factor for these high scores compared to the other groups is the cancer it self. Cancer is a life threatening disease and can affect many aspects of a patient's life. Therefore, cancer has a stronger motivational and arousal effect on patients to learn what will help them in the decision making process and in sailing through the difficult times of treatment and subsequent rehabilitation.

On the other hand, non-cancer and pre-cancer patients are on regular review visits to the oral medicine clinic due to their chronic disease or other conditions. Management was directed mainly to monitor the signs and treat the symptoms if present as a result of the disease. The main (probably the only) source for information and support to patients in the clinic is the consultant or his specialist registrar. Patients may have a systemic disease

which affects other parts of the body; and thus managed by one consultant but may see other specialists separately at different time and place.

The non-cancer and pre-cancer patients in this study share the lack of information in the following items from the overall management; the aetiology of the disease, treatment side effects, prognosis, support groups and psychological effect of the disease. These subjects may need to be discussed in more details with patients.

1.5.2 Source of information

In section C, patients were asked to rate four sources of information: the specialist, the dentist, the general practitioner and the nurse (section 1.4.4). The fact that the majority of the patients (94%) ranked their consultant as a good source for information is consistent with other studies where the consultant was the best source for information (Chalmers et al. 2001, Mills et al. 2002, Walter et al. 2004); the dentist is in second place as ranked by 47% of the patients as good, this was expected as majority of patients have problems related to their mouth.

The general practitioners were considered as a poor information source for oral cancer patients (Mills et al. 2002). In this study, the GP was in third place as only 35% of the patients ranked GPs as a good source for information. This is of concern as there is a much higher chance for a patient going to see his GP rather than his dentist for a routine check up or for occasional illnesses, and regular mucosal examination will increase the chances of detecting oral cancers at early stages. A survey of hospital doctors' knowledge and attitude of oral conditions recommended more GP education about oral diseases, specifically how to make a diagnosis of oral squamous carcinoma (Morgan et al. 2001).

The oncology nurse role was emphasized when ranked as good, by 48% of the patients, however this may only reflect the oral cancer patients' opinion as it was ranked mainly by oral cancer patients (80%). The oncology nurse plays a significant role in providing support to patients in many forms, and helping patients overcome casual problems encountered when attending different hospital departments for treatment (Semple et al. 2002).

1.5.3 Need for additional information and from whom

In section-D patients were asked if they wished for more information and from whom (consultant, dentist, general practitioner). Seventy nine patients answered this question, 68% did not want more information and 32% (25 patients) did ask for more. These patients were 14 pre-cancer patients, 8 non-cancer patients and 3 cancer patients.

The lack of (and possibly the desire for more) information in the non-cancer and pre-cancer patients was not focused on in specific items, however, four items were shared by the two groups and reported on more than the others, disease aetiology, prognosis, disease emotional effect and support groups (section 1.4.5). Support groups may not be of concern to the non-cancer or pre-cancer patients (Chalmers et al. 2001) but the role of other patients with similar conditions as a source for information is well recognised in cancer and non-cancer patients (Maldonato et al. 2001, Wolf 2004a). The other three subjects have already been highlighted in previous researches (Fallowfield et al. 1999, Meredith et al. 1996).

Three oral cancer patients did lack information on prognosis, emotional support and support group. Such information was available for this small group of patients as it was for the others, however, this shows the difference in patient's ability to use and absorb

available information and also highlights the importance of communication between members of the multidisciplinary team so as not to allow any patients to slip through the system. The patients' selection for sources other than the consultant (i.e. dentist and GP) supports the literature that they would benefit from more than one source of information.

1.5.4 Patients need and preference for format of additional information

In section-E, patients were asked to rank their preference for five different formats used in patients' education: written format, video format, audio format, personalised computer software, and the internet (section 1.4.6). The response rate was 51% only, this is mainly due to some patients choosing one format only or missing the question completely, and patients needed to rank at least two formats to include his/her answer.

Written format: The majority of patients considered the written format as the most preferred form for additional information materials compared to the other formats listed. Thirty five (35) out of 54 patients (65%) ranked it as the most preferred form and 10 patients (18.5%) as the more preferred form. There was no preference for any specific group of patients to this form. The high ranking can be explained by many reasons, such as it is the most popular form used in patient education, patients are very familiar with it, it is amenable to many different groups of patients, it doesn't need additional technology to use, and it is cost effective if it satisfies its objectives.

Written information is the most widely used form in cancer education (McPherson et al. 2001). It has been used for many purposes, including establishing the concept of partnership in patient care and the decision making process, for increasing patient satisfaction, for controlling preoperative anxiety and for changing a patient's cognitive behaviour (Barlow et al. 1998, Boundouki et al. 2004, Mazor et al. 2003).

It has many advantages and considered as the standard for comparing newly developed educational forms (Humphris et al. 1999, Ream et al. 2003, Semple et al. 2002, Treacy et al. 2000). The main advantage of printed education materials is that they are well established, backed-up with a great deal of research and are they are popular amongst patients. Providing educational material in the written format has the advantage of giving the choice for people to read the details at their own pace and ability to review the topics when desired. Also, printed materials are accessible everywhere, anytime and allow the content to be easily shared with family and friends.

Researches have reported positive short term outcomes, such as control of preoperative anxiety and better understanding of disease and treatment options, from well designed printed information materials. However, this form of education has been criticized for the knowledge gained from reading printed materials can often diminish with time if patients do not repeatedly read the material (Boundouki et al. 2004, Mazor et al. 2003). Also, in written format there is a limit to what you can include in a booklet or leaflet, and there is no feedback from the patients (lacks interaction), and the message is usually not personalised.

Video format: Patients in this survey ranked the video format as the second best to the written format where 24% ranked it as most preferred and only 14.8% as the more preferred to other formats. However, surprisingly 27.8% of the patients did not favour it at all and 9.3% less preferred it. This could be because patients are not familiar with this form of educational material, although video educational material for patients has been used so far in specific group of patients. Also, this may reflect a new theme in people moving from video cassette to DVDs.

Video format is another method used in cancer patients' education; it was regarded as a useful additional information strategy within routine oncology practice (Dunn et al. 2004, Thomas et al. 2000). Videotape has the same advantages of written information and can be useful in educating people with low literacy skills or those with visual impairment affecting their ability to read printed materials. Research found that video instruction was effective in a number of ways: supporting the verbal consultation; in carrying on education outside the clinic; increasing knowledge for the short term, and reduction of psychological arousal. However, it has little effect in the long term retention of information and for changing behavioural practice (Doering et al. 2000, Krouse 2001, Thomas et al. 2000).

This method of patient education is not without its shortcomings; it is more expensive and requires a professional media cast to produce and update (e.g. TV personalities). It is not recommended for specific issues related to disease, surgical procedure or prognosis (Thomas et al. 2000). Also, the requirement of a video player and television to use the medium may limit its usage. More research is needed as to the value of video modelling in informed decisions compared to traditional teaching models and the long term effects of video modelling on long term self care and its consequences on behavioural outcomes (Krouse 2001).

Computer based format: Only 5 patients (9.3%) think that the CD-Rom format is superior to the others, while 21 patients (38.9%) consider it the last option. It is ranked third in order of preference after the video format, with no preference noted from any specific group of patients. The internet format was in a similar position as the CD-Rom format placed after the video format. Nine patients (16.7%) preferred it to the others, however 25 patients (46%) least preferred it especially by the cancer patients group.

The rapid expansion of internet access has opened a new dimension for patient education and the internet became a popular source for medical information. The number of patients using the internet to gather information about their diseases, treatment options, medications and self care is increasing. There are several advantages of the internet to patients including the convenience of access to and interaction with unlimited health information, and being in total control over the rate of learning. Therefore, it can provide a more relevant (tailored) information source which may facilitate learning. The common positive impacts that computer based education has are on knowledge acquisition and doctor-patient communication (Boudioni et al. 1999, Lewis 1999, Oermann 2003).

A major disadvantage of internet information is its lack of regulation; information provided on the web has been criticised for its credibility, accuracy and lack of control (Oermann 2003, Smart et al. 2001). Standards have been proposed for presenting health information on the web by health professional organisations, but adherence to it is however voluntary. Therefore, it is important for the health professionals (e.g. nurses) to ensure that patients are directed to web sites that present accurate, comprehensive, and current information.

CD-Rom information package is one way to overcome some of the disadvantages of the internet (Gatherer 2000, Liedholm et al. 1996). This method has been used previously in dental implant patients (Barkhordar et al. 2000) and in breast cancer patients (Street et al. 1998) with a satisfying outcome. However, patients in both studies were younger (mean age is 50 years) compared to oral and pharyngeal cancer patients where the mean age is usually 60-65 years.

One of the main limitations for the internet usage reported in the literature is the ability or willingness of elderly people to use computers for education (Lewis 1999). Some health care professionals attempted to simplify the computer based education technology by using touch-screen computers or large and fewer key buttons; however, this would be of no value if patients are simply not interested in this form of information material.

Audio tapes: Audio tapes have been used previously in improving information recall in oncology patients and self-care after treatment (Hagopian 1996, McHugh et al. 1995). In this survey, audio format was the least preferred by patients; none of the patients preferred it to the others and it was the least preferred by 29 patients (53.7%).

1.6 Conclusions

This survey highlights the need for continuous, consistent and repeated communication of information at different times from different people using different dialogues. Also it highlights the significant role of specialist clinical nurses in supporting the information delivery to patients. This information delivery system is reproduced in the management of oral and pharyngeal cancer patients at the maxillofacial unit but not at the oral medicine clinic. This suggests that the information delivery system is adequate at the maxillofacial (oncology) unit and additional educational intervention may not have a measurable impact on oral cancer patients. Further improvement in patient's information level is better applied through the present system by providing patient with readily accessible multiple on-site sources for information for tailored information. Patients in oral medicine clinic may benefit from the nurses knowledge and experience in providing information and psychosocial support.

This survey also highlights the lack of patient's confidence in dentists and general practitioners (GPs) as sources for information. This lack of confidence can be improved through encouragement of dentists and GPs to be more involved in the management of oral diseases as they play an important role in the care of chronically ill patients.

The written format was the most preferred format in this group of patients. However, video format can have role in special group of patients such as illiterate patients. The use of computer format or audio tapes format for delivering information may not be appropriate at this time for this group of patients.

Patient's level of knowledge about various aspects of their disease and type of information needed at different point of management as well as additional information patients would have liked were not assessed in this study. A further study explored these issues (chapter 3) in a qualitative method including open-end questions for patients to express their needs freely.

There are some limitations in this study that prevent us from generalising its results. The sample size was small and there was no record of patients' refusal from the oral medicine clinic. Better technical arrangement in the future and a longer period of recruitment may resolve these issues. As this was a cross sectional design study with a locally developed questionnaire, the questionnaire validity, reliability and sensitivity have not been tested. Thus, future applications need to test it against other available information need and/or satisfaction questionnaires. There needs to be more emphasis on open ended questions and giving patients more space for free text answers to express their individual needs and comments. Moreover, patient's information needs is dynamic and change over time; also, it depends on the patient's psychological/physical state and disease treatment

stage. Therefore, a prospective longitudinal study design is more appropriate to assess patient's information needs taking into account the patient's mental and physical state as well as the disease characteristics.

One of the goals in providing patients with different types of information materials in hospitals is to reduce their level of anxiety and consequently improve their HRQOL. The purpose of chapter 2 is to explore the issue of anxiety and its relationship to HRQOL in these highly satisfied patients with information delivery system. It is noteworthy that based on the results from this study, the C.D.Rom informational package planned to be used in patients' education in the next study was reproduced as a written informational booklet in accordance with the patients most preferred format.

Chapter 2

2. Anxiety and Health related quality of life

2.1 Review of the literature

2.1.1 Anxiety in Head and Neck Cancer Patients

2.1.1.1 Introduction

The physiological response of anxiety was recognised in the late 18th century. Modern psychiatric theorists believe that all physical diseases have psychosocial components; these components may predispose to, initiate, or maintain illness.

Freud first recognised anxiety as the core symptom in anxiety disorders and introduced the term "anxiety neurosis". He believed that the psychological symptoms of anxiety (patient's inner subjective feelings) were primary and led to the development of physical symptoms. Others, such as Dunbar, Friedman and Rosenman believed the contrary to be true, that anxiety is the product or the manifestation of the physical symptoms. The relative relationship between the physical and psychological symptoms of anxiety (although well established) remains a matter of debate to which is primary and which is secondary (Goldman 2000).

The word "anxiety" describes an unpleasant emotional state with feeling of apprehension, anticipation, or fear of possible danger with no associated clear source of danger. Anxiety can range from simple worries to obvious unsteadiness and to complete panic in severe forms of anxiety; the course of which and duration can vary from a few seconds to hours or days or even months. Anxiety is frequently accompanied by physiological symptoms such as autonomic arousal, alertness, vigilance, and motor tension which may lead to fatigue or even exhaustion. Fear is similar to anxiety although is recognized as an unpleasant emotional and physiological response to a recognised external

threat. Both fear and anxiety set off comparable unpleasant mental and physical changes and patients frequently use both terms interchangeably. Phobia is severe anxiety provoked by a specific object or circumstance even though the subject knows the feeling "doesn't make sense" (Goldman 2000, Kaplan et al. 1995).

Anxiety disorders have a 6-month prevalence of 6.8% in individuals aged 65 and older, and are more common in women. It is 4-7 times more common than major depression in older adults (Beck et al. 1996). However, one must consider the current estimates as a rough approximation for the following reasons:

- Older adults are often reluctant to report psychological symptoms.
- The present epidemiological studies do not consider older adults living in institutions that are likely to have higher rates of anxiety.
- There are many older patients with subsyndromal symptoms sufficient to disrupt their lives, nonetheless do not meet the standard criteria for anxiety disorder.
- It is not clear whether the current assessment questionnaires address the experience and presentation of anxiety in older adults as it does in young adults (Kogan et al. 2000)

2.1.1.2 Anxiety development

Individuals diagnosed with serious medical disease like cancer may experience a profound grief reaction such as feelings of shock, disbelief, and emotional numbness. Grief and mourning are commonly related to the anticipated or actual loss of competence and bodily integrity and to the disruption in the expected course of life-span or accomplishments (Brown et al. 1983). This response may be followed by a phase of denial

of the actual reality of the illness or a switch to unavoidable alertness of the illness (arousal state). Oscillations between denying the implications of the illness and feeling overwhelmed by it are common (Razavi et al. 1994b). Denial has an adaptive value in the short term, however, adaptation to chronic illness is usually more effective when feelings related to the condition can be acknowledged, expressed and dealt with. There is a broad range of feelings related to the illness that may be experienced as well, after the initial response to grief (Stak et al. 2004); nevertheless, there are wide individual and cultural differences in this regard.

When anxiety is so intense or persistent to the extent of interfering with normal daily functioning it becomes maladaptive and is properly diagnosed as disorder (Jefferson 1996). Some clinicians require at least three of the following six symptoms to qualify a person for the diagnosis of anxiety: restlessness or feeling keyed-up; being easily fatigued; difficulty concentrating or mind going blank; irritability; muscle tension; sleep disturbance (difficulty falling or staying a sleep, or unsatisfying sleep) (Goldman 2000). The boundary between normal and pathological anxiety cannot be drawn with great precision or confidence but most authorities agree that careful assessment is indicated and treatment is worthwhile when anxiety substantially impairs work or social adjustment (Kogan et al. 2000). Most patients with primary depression complain of feeling anxious, worried or fearful; equally, primary anxiety can be depressing in its own right and long standing anxiety that interferes with function is likely to be comorbid with secondary depression (Kessler et al. 1999).

There are numerous studies in the literature demonstrating the link between a psychological state and a physiological state predispose individuals to diseases such as reduced autonomic arousal and age, the increase of resting systolic/diastolic blood pressure

and age, and type A patient. Nevertheless, they are still searching for the mechanisms of how this actually occurs (Cohen et al. 2001, Kogan et al. 2000, Morgan III et al. 2001).

2.1.1.3 The DSM-IV:

The Diagnostic and Statistical Manual of Mental Disorders, 4th edition, (DSM-IV) represents the standard classification of mental disorders used in the United State and internationally. It is the culmination of extensive systematic and analytical research for studies in the field of psychiatry by an unprecedented number of individuals and field trial assessments for reliability of the several suggested criteria sets included in the previous manual (DSM-III-R) and ICD-10. The DSM-IV classification system is compatible with the ICD-10 and both systems provide accurate, well defined, and highly reliable diagnosis in clinical psychiatry (Bertelsen 1999, Goldman 2000).

Generally, the DSM-IV organises mental disorders according to 16 major diagnostic classes based on common presenting symptoms to facilitate differential diagnosis. Anxiety can be a main feature of the major diagnostic class (Anxiety Disorders) or it can be one of the features (similar to depressed mood or disturbance of conduct) that sub-classify the major diagnostic class (as in Adjustment Disorders). There are 12 categories of anxiety disorders in the DSM-IV, and to be diagnosed with anxiety, a patient must meet a number of criteria for that disorder (Endler et al. 2001, Goldman 2000).

The criterion of clinical significance was added to the criteria set for a large number of diagnostic categories to solve the false positive problem recognised in the DSM-III; the clinical significance criterion requires that the individual exhibit "clinically significant distress or impairment". Although this criterion was used in some of DSM-III-R categories

(e.g. social phobia, simple phobia and obsessive-compulsive disorder), its wholesale application in DSM-IV was heavily criticised (Spitzer et al. 1999).

2.1.1.4 Types of anxiety:

The Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) classifies anxiety according to whether it is persistent, and called Generalised Anxiety Disorder, or episodic. Episodic anxiety can further be divided into Phobia if sparked off regularly by the same trigger or Panic disorder if not. The following are types of anxiety most related to head and neck cancer patients:

Generalised Anxiety Disorder (GAD) is one of the most common in the elderly. It was first recognised as a disorder in DSM-III (1980), however, the status of GAD has been changed from that of residual category in DSM-III (only diagnosed when all other disordered were excluded) to that of a distinct diagnostic category in DSM-IV (Rogers et al. 1999a, Slade et al. 2001). It is defined as a chronic disorder characterised by fluctuating levels of incontrollable worries during a period of at least 6-months and associated with elevated autonomic arousal (such as palpitation, insomnia, and irritability) and cognitive symptoms (such as poor concentration and hyper-vigilance) (Beck et al. 1996). The "clinical significance" criterion (added in the DSM-IV) requires the symptoms to be excessive and have a duration for at least 6-months with an increased emphasis on worry and secondary psychic symptoms by elimination of most somatic symptoms (Slade et al. 2001). Age distribution was similar for GAD, though older adults with GAD appear to have heightened reports of anxiety, worry, depression, and social fear (Beck et al. 1996). The symptoms were criticised as being vague and overlapping with many other anxiety disorders, however, most studies have supported the diagnosis of GAD as a valid disorder (Rogers et al. 1999a).

GAD can be of two types, primary or secondary based on the aetiology although both have the same course and clinical manifestation. The primary GAD has early onset (late teens to early twenties) and individuals have a high rate of depression. In the secondary GAD individuals are likely to have a history of alcohol intake, pre-existing other anxieties (i.e. residual anxiety), depression, or drug abuse. Co-morbidity such as excessive medical utilisations or unexplained somatic presentation or other mental disorder is common and a major issue for both types regardless of the cause (Mennin et al. 2000, Rogers et al. 1999a).

Subsyndromal or minor GAD patients are those who fail to meet all diagnostic criteria for the GAD. This group of patients are distinguished from GAD patients by three diagnostic criteria; they worry more days than not, have difficulty controlling worry, and clinically have significant distress or impairment (Diefenbach et al. 2003). Yet, complexities in diagnosing anxiety among elderly adults (e.g. increased medical co-morbidity) suggest that identifying subsyndromal symptoms particularly in this age group will be more difficult.

Some people with no previous psychiatric history may develop what is called ***Acute Stress Reaction*** in response to an extremely stressful physical or psychological event. The characteristic symptoms of this condition include a sense of anger, over activity, numbness, amnesia, confusion and withdrawal. This state may followed by both further withdrawal and depression or anxiety and over activity. Also, it is not uncommon to have signs of arousal including tachycardia, sweating and hyperventilation. Such a reaction is transient and usually subsides within hours or days at the most. Provoking events may be an overwhelming traumatic experience or sudden change in the social circumstances of the individual such as bereavement (Kumar et al. 2002). Of course not all people exposed to

such stressful events develop this reaction, which is due to the variation between people's ability to cope and the severity of the acute stress reaction.

The most common psychological response to physical illness is ***Adjustment Disorder***. It can follow an acute stress reaction, after bad news or following a significant life event. The DSM-IV defines the adjustment disorder as "significant emotional or behavioural symptoms in response to an identifiable stressor occurring within three months of the onset of the stressor". The reaction may take the form of either "marked distress in excess of what would be expected" or "significant impairment in social or occupational functioning". The symptoms can vary from disturbance of conduct to depression or anxiety or both, however, symptoms are not sufficiently intense to justify the diagnosis of other mental disorders like Anxiety disorders and where the duration of symptoms does not exceed 6 months (Goldman 2000).

The presumed mechanism of adjustment disorder is disruption of the normal process of adaptation to a stressful life event. A model of normal adaptation described by Horowitz (1997) depicted four stages that a person experience during this process. First, the person protests against what has happened and common reactions are objection, tearfulness, sorrow and sleep disturbance. This is followed by a phase of intrusion during which the person is painfully aware of what happened or denies it completely becoming ignorant to the new reality which could last several weeks. The person will gradually start to work through the new situation when he is better able to integrate the event and complete resolution is marked by the physical and functional recovery to the person's normal daily life activities (Horowitz 1997). In adjustment disorder, this process of adaptation does not proceed to completion due to a stress overload to the level that exceeds the individual's ability to cope (Razavi et al. 1997, Thompson et al. 2001).

Adjustment disorders do not usually require psychotropic medication and patients are expected to recover after the stressor ceases or when a new level of adaptation is achieved. Generally, explanation and reassurance are essential in the management of all forms of anxiety. It is recommended for patients with adjustment disorder to have a brief treatment with periodic reassessment to relieve symptoms and foster a positive change whenever possible. Other psychosocial treatment includes individual behaviour therapy; supportive and expressive psychotherapy; family counselling; and self help groups. When the patient feels out of control, appropriate medication may be used to reduce symptoms to a manageable level for the patient to begin coping with the stress. Drugs have a limited role and are generally considered adjunct to treatment or as backup treatment when psychological treatments are not available or unacceptable to the patient (Ohayon et al. 2002, Razavi et al. 1994a, Rehse et al. 2003).

Social anxiety, also known as social phobia, is a common anxiety disorder characterized by a fear of inspection by others, with victims experiencing excessive anxiety in both social and work places. This excessive anxiety usually leads to avoidance behaviour that can severely disrupt normal daily activity and impair the development of social and personal relationships (Wittchen 2000). It is not uncommon in patients with neurotic disorders such as panic and generalized anxiety disorder and its differential diagnoses are agoraphobia, panic disorder, stress disorder and avoidance personality disorder. However, there are two essential elements for the diagnosis of social phobia situational fear and avoidance. Also, paying close attention to the nature of the places in which fear is shown should distinguish it from agoraphobia. Social phobia in the long term (untreated) is often co-morbid with depression, other anxiety disorders, alcohol and substance abuse (Brunello et al. 2000).

Anxiety associated with phobic avoidance was the most frequently reported difficulty in a group of plastic surgery patients especially in social situations (Newell 2000). Altered body image is a potential source for considerable distress, particularly following facial disfigurement. Facially disfigured people can experience a high level of anxiety and significant psychological problems, commonly relating to difficulties in social interaction (Robinson et al. 1996).

A study by Newell and Mark (2000) established the relationship of facial disfigurement and social anxiety; they compared the scores in two standardised questionnaires for social phobia and anxiety/depression for the two groups. They found that people with established social phobia and people with facial disfigurement have similar social phobia scores and anxiety/depression sub-scores. This indicates that facially disfigured people are likely to have social phobia and deserve the cognitive-behavioural therapy that is effective for such phobias (Newell et al. 2000).

Body image reintegration is critical to subsequent quality of life and features of body image reintegration include ability for self care, re-socialization, and reduced anxiety (Dropkin 1999). A quality of life study on facially disfigured head and neck cancer patients shows that this group of patients do not necessarily develop poor quality of life(Vickery et al. 2003), however, another study reported that head and neck cancer patients with greater disfigurement were more depressed than patients with subtle or no disfigurement (Katz et al. 2003). Future studies need to establish the prevalence of social phobia in head and neck cancer patients and its relationship with their quality of life.

Facial disfigurement research indicates that the adjustment process involves the way that people interpret their disfigurement and their encounters with others. Therefore,

psychological adjustment problems in facially disfigured people can be managed by different treatment modalities including psychodynamic, behavioural, and pharmacologic treatment as well as by working with family members and staff. Cognitive behavioural therapy, with or without specific antidepressant therapy, is the evidence-based treatment of choice for most patients (Razavi et al. 1994a, Thompson et al. 2001).

2.1.1.5 Measuring Anxiety

Depending on the personality type, anxiety can be classified as trait anxiety or state anxiety. Trait anxiety originates from the personal internal attitude and thoughts that influence his behaviour and self-representation (the threat is internal); therefore, affected individuals behave at the same level of anxiety across all situations (stable personality disposition reflecting general level of fearfulness). State anxiety is a transient heightened state of anxiety that varies according to the situation such as in medical or financial problems (the threat is external) (Caumo et al. 2001). According to Endler et al (2001) both types are multidimensional construct. There are at least four components for trait anxiety: social evaluation, physical danger, ambiguous, and daily routine; and two components for state anxiety: cognitive-worry and autonomic-emotional. Some view anxiety as a continuum (unidimensional), when one end represents a low amount of anxiety and the other end represents a severe level of anxiety. Another traditional approach in psychiatry is the categorical approach, where a patient either has a disorder or not. Categories are helpful in communication by simplifying matters, although, the dimensional approach results are more informative (Endler et al. 2001).

Anxiety diagnostic assessment instruments vary according to the theory it is derived from. For example, The State-Trait Anxiety Inventory (STAI) considers anxiety as uni-dimensional where the Endler Multidimensional Anxiety Scale (EMAS) assesses both state

and trait anxiety as multidimensional. Although most of the available instruments have sound psychometric properties, it is important to assess anxiety using various techniques. One can use behavioural and physiological measures in addition to self-rating instruments (Endler et al. 2001).

Anxiety in older adults is different from that in young individuals; this is due to age-related changes and mainly to the autonomic nervous system. The available self-reported measures should be used with caution when assessing anxiety in elderly adults. This is because most of the instruments are designed for the younger population (e.g. activity and interest are different), and the increased co-morbidity with psychological and/or medical disorders (e.g. depression), and many of the available instruments are also influenced by somatic symptoms. Therefore, proper instruments for older adults should not be influenced by physical symptoms but should address psychological aspects most relevant to this group of people (Kogan et al. 2000).

The Hospital Anxiety and Depression Scale (HADS) was developed by Zigmond and Snaith in 1983 with special attention to some specific issues relevant to the setting of somatic medicine (Zigmond et al. 1983). The scale was limited to 14 items, and the investigators omitted physical indicators of psychological distress and several psychopathological symptoms were not covered. This is in attempt to:

- Make it easy to administer and more acceptable
- Make it more sensitive to mild forms of psychiatric disorders
- Not to be influenced by physical symptoms common in older adults in hospital patients

- The scale should not be over-responsive to transient fluctuation states which may occur in situations such as coming to the clinic (e.g. headache or fatigue)

- Respond well to mood changes which may occur during the course of the disease or treatment (Herrmann 1997).

Thus, the scale is designed to measure prolonged state rather than trait anxiety and depression. The scale is reported to have good psychometric properties in medical patients (including cancer) and the general population (Bjelland et al. 2002). This qualifies it to be a good screening tool for anxiety or depression in older adult on treatment. Though, for the diagnosis of anxiety it should be augmented with other techniques such as self-report anxiety instruments, clinician-rated instruments, direct observation or physiological measures.

2.1.1.6 Anxiety in Head and Neck cancer patients

Patients submitted to surgery commonly experience anxiety (Caumo et al. 2001), and many patients referred to the oral and maxillofacial clinic for consultation tend to be in a state of anxiety. Those patients have a low level of knowledge about head and neck cancer (Edwards 1998, Humphris et al. 2001). In a multicentre study, Hammerlid et al (1999) assessed psychiatric morbidity in a large heterogeneous sample of newly diagnosed patients with head and neck cancer using the HAD. They reported the highest number of patients with caseness (possible) for anxiety at the preoperative stage (32%) with a gradual decline up to one year (20%). However, the percentage of patients with caseness for depression was 17% at the preoperative stage, which increased to 24% at the 3-month stage then declined gradually to reach 17% at 1 year. The anxiety level was highest at diagnosis, while depression was more common during treatment (Hammerlid et al. 1999a).

Anxiety may be linked to expectation about pain, physical discomfort, to fear about the unknown inside the body, to negative attitude of outcomes or simply not being in control (van balen et al. 1999). Contradictory information was also a source of anxiety for most patients (Leydon et al. 2000). Patients with head and neck cancer have to struggle with many losses such as normal facial appearance, speech, taste and smell. This enormous threat to self image, confidence and identity can be a cause of many psychological problems including depression, which might continue in survivors for a long time despite decreasing medical problems (Kugaya et al. 1999, Rapoport et al. 1993).

2.1.1.7 Predictors of postoperative anxiety

A large study has carried out on adult patients going for elective surgery under general anaesthesia looking at the risk factors for postoperative anxiety. They found that patients with poor physical status (ASA status III), history of smoking, moderate to intense pre-operative pain, minor psychiatric disorder, preoperative state-anxiety and negative preoperative self-perception of the future, recognised as risk factors for postoperative state-anxiety (Caumo et al. 2001).

Similar study was done on back pain patients going for lumber surgery. They found pre-operative state anxiety and pain predicted postoperative anxiety, independent of gender or age (de Groot et al. 1997). Hammerlid et al. (1999) in a prospective study of psychiatric morbidity in head and neck cancer patients found that the baseline anxiety and depression level significantly predicted anxiety and depression at one year. They also found a strong correlation between lower performance status and higher level of psychological distress (Hammerlid et al. 1999a).

Avoidance coping style (denial, giving up or withdrawing) and suppression of competing activities (focus exclusively on the illness) were the most characteristic seen in patients treated for head and neck cancer (Sherman et al. 2000). However, researchers found that coping behaviours, preoperative trait-anxiety, extent of surgery and HRQOL baseline measures did not constitute a risk factor for postoperative anxiety (de Groot et al. 1997, Rogers et al. 2000).

2.1.2 Health related quality of life (HRQOL)

2.1.2.1 Introduction

The application of HRQOL assessment is important in a variety of clinical settings such as symptom control (disease or treatment related), management of cancers with poor prognosis, and for supportive care intervention (Osoba 1999). Most of the rehabilitation outcomes are related to the type of treatment and one of the research goals on quality of life in cancer patients is to give a thorough description of the recovery course and the rehabilitation thereafter (Mossman et al. 1999b). Also, quality of life measurement is required by policy makers to make reasonable judgments about benefits of different treatments (Morris 1993).

"Quality of life" is a collective term summarizing a range of related, interacting dimensions and the term has been used as a concept and as an instrument of measurement (Bloom 1991). The definition is considered very broad by many researchers with no agreement on a validated meaning, however, they do agree on a number of issues. First, they agreed that quality of life contains four basic dimensions: physical status, psychological wellbeing, social relations, and functional capacity. Second, they agreed that quality of life is a subjective evaluation and the patients are the best judges of their own

quality of life. Third, quality of life is not static, but a dynamic matter. This means that quality of life is a time-dependent process rather than a final outcome (Kiebert 1997).

Although the government generally has concern for the patient's quality of life, the clinicians' role in the assessment of patients' quality of life is limited to dimensions that are both health related and health sensitive. These include physical, psychological and social functioning, disease and treatment related symptoms. Also, the choice of quality of life domains to be assessed are controlled by the patient population in the search, the nature of the applied therapies and the research question at hand (Aaronson 1991).

Quality of life can be considered as equivalent of a rehabilitation outcome, and the terms are often used interchangeably. In this concept quality of life basically means the person's perception of his/her ability to function in meaningful areas of living, after illness, as compared with before (De Boer et al. 1999, Dolbeault et al. 1999).

Symptoms generally represent the patient's experience of the physical aspects of cancer progression and treatment. Distress refers to the patient's experience of the psychological impact of cancer and its treatment and includes depression and anxiety. Functional abilities measure the impact of cancer on patient's activities and range of movement including routine daily activities. Social well-being refers to maintenance of social support, and relationships with significant others (Owen et al. 2001b).

Because cancer is a debilitating disease and life expectancy is shortened for many patients, quality of life during and after treatment is of paramount importance (Mossman et al. 1999b). Medical and surgical advances in the management of oral and pharyngeal cancer have led to the increase in the number of years for patient survival, hence patients today carry on cancer symptoms and treatment side effects for a longer period of time than

before (Edwards 1998). This call for a more detailed description of disease related morbidity is in order to better evaluate the new competing interventions and to justify decisions to provide supportive care. HRQOL assessment is expected to improve management outcomes by putting more emphasis on the emotional, social, and functional aspects of patients' well-being (Wan et al. 1997).

Oral and pharyngeal cancer is a life threatening disease. Patients who are affected by the disease have to deal with both the impact of the disease and its treatment on appearance, self confidence, identity and important functions such as eating, swallowing, taste, smell and speaking (Rogers et al. 1998a). Due to the relatively late presentation of patients affected by the disease, the combined treatment of surgery and radiotherapy became the plausible approach in the management of oral and pharyngeal cancer; and radiotherapy has long-term side effects which significantly affect long-term survivals quality of life (Klug et al. 2002).

Unlike other cancer surgeries, minor disturbances of anatomy by surgery in the oral and pharyngeal area may lead to significant dysfunction and disfigurement and this group of patients cannot hide their disfigurement. Therefore, head and neck cancer has been described as a psychologically highly traumatic cancer type (De Boer et al. 1999, de Graeff et al. 1999).

Improvement in surgical skills with refinement of reconstructive techniques and more sophisticated radiotherapy have made treatment of more advanced tumours possible with a more acceptable functional and cosmetic outcome, and these changes also have a positive influence on loco-regional tumour control. The 5 years survival rate in the past decade has stabilized at about 50% (Langdon 1995). However, there has been some

progress in the research of head and neck cancer quality of life and considerable growth in the development of specific head and neck instruments over the last two decades (De Boer et al. 1999). The need for cancer specific QOL instruments was highlighted as comparable survival rate and quality of life for advanced oropharyngeal cancer patients after surgical or radiotherapy treatment was noted. Stresses are on the use of treatment-specific domains in QOL assessment for more sensitive outcomes (Deleyiannis et al. 1997).

2.1.2.2 Methods of assessment

There are two distinct approaches in assessing quality of life. One way is to operate quality of life in a multidimensional framework using traditional questionnaires. This work is important if we intend to use these instruments for identifying the at risk population of cancer patients or for comparing quality of life across chronic disease populations. The second approach to assessing quality of life is from the economic point of view and uses the concept of Quality Adjusted Life Years. This is a more recent method of research in health studies and it correlates the individual preferences for specific health states (i.e. quality of life) with treatment. Such utility methods, borrowed from economics, may be especially useful in applying quality of life assessment at the level of clinical decision-making (Aaronson et al. 1991).

Questionnaires are a popular method used to measure health status which, broadly speaking, adopts two general approaches; "health index" that provide a single global score of well being, and "health profile" which measures a number of dimensions of health status. The superiority of one method to the other in usefulness and reliability of measuring health status is debatable, however, health economists favour the health index approach as it gives a single index figure which can be used mathematically with other variables (e.g. cost and life expectancy) to determine which treatments are of low or high priority in terms of

efficacy and cost. Health profile measures are not intended to do this even some of them can; they are intended to provide valuable, thorough and concise information about areas that may adversely be influenced by illness or its treatment (Bowling 1995).

2.1.2.3 Advantage of HRQOL assessment

Quality of life has many function in cancer management such as informing, development, implementation, application of public policy and considering human value preference in oncology (Aaronson et al. 1991, Morris 1993). QOL assessments have been used successfully for a variety of objectives within oncology such as:

- Improving patient-doctor communication; HRQOL assessment supports the concept of patient-centred intervention (Osoba 1999).

- Few studies have indicated that HRQOL results can have a prognostic and predictive value in oncology. They argued that patients' HRQOL status are more informative than performance status alone as a prognostic indicator for survival (de Haes et al. 2000, Osoba 1999).

- Improve the patient's decision-making process. HRQOL assessment makes hidden values of treatment clear and describes the nature and extent of functional and psychosocial problems confronting patients at various illness management stages (de Haes et al. 2000); therefore, it provides a better setting to get informed consent.

- It provides significant data when assessing the cancer burden on survivors, as it compares cancer to non-cancer populations, and describes changes over a period of time (Bloom 1991).

- HRQOL assessment screens patients for further psychiatric evaluation.

- It aids in monitoring the quality of care. In order to improve services delivered, quality of care assessment in hospitals or specialised units should be routinely measured in addition to other traditional measures (Bloom 1991).

- It helps in evaluating the patients' benefits and losses (relative effectiveness) that may result from competing medical or psychosocial interventions (Kiebert 1997).

2.1.2.4 HRQOL in oral and pharyngeal cancer patients

Most of the QOL studies in head and neck cancer patients are criticised as being descriptive, retrospective, focused on physical morbidity, and with little reference to how QOL is influenced by the stage of disease (Morris 1993). However, much of these remarks are prevailed in the more recent HRQOL researches (Rogers et al. 1999b).

Rogers et al (1998) prospectively assessed the HRQOL of 48 oral and pharyngeal cancer patients over a period of 12-months using the SF-36 and the UW-QOL questionnaires. They found an association between larger tumours and increased pain, and there were lower scores for cancer patients than norms in three SF-36 domains (physical role limitation, mental role limitation and social functioning) at presentation. They also found the SF-36 questionnaire to be sensitive to change over time following surgery for oral cancer (Rogers et al. 1998a).

Rogers at al (1999) compared the QOL in two groups of oral and pharyngeal patients, 25 disease free patients at one year and 38 disease free patients after 5-10 years. Both groups continue to experience severe problems with chewing, disfigurement, emotional functioning, cognitive functioning, and chewing related functions such as dry mouth and sticky saliva. It was concluded from this study that, in the absence of major

biases, the patients' response at one year following surgery is a useful indicator of the long term gain (Rogers et al. 1999c).

Based on the cumulative score of the UW-QOL at baseline, Rogers at al (2000) were able to identify two groups of patients who similarly, over one year, had a dip at 6-months and a tendency to return to pre-treatment values by 1 year. Both groups remained distinct from baseline; patients scoring less favourably at baseline continue to do so following treatment, however, the pattern was similar in both groups (Rogers et al. 2000). In the same study, Rogers at al (2002) used a clinician rating scale and were able to predict the cumulative UW-QOL score, they concluded that functional deficits at presentation persist following treatment (Rogers et al. 2002).

Shepherd and Fisher (2004), in a study for the changes in HRQOL in the short term (3-months) after treatment found a significant increase in symptoms scores and a decrease in functional scores starting as soon as 2-weeks after treatment (shepherd et al. 2004).

Hammerlid et al (1997) reported that oral and pharyngeal cancer patients treated with radiotherapy are at their worst physical and functional QOL scores 2-3 months after the start of treatment but gradually improved thereafter. The researchers recognized these peak values to be an acute toxicity reaction to the radiation, which subsequently subsides. At 1 year follow-up, the main complaints were: pain in the mouth; eating and drinking problems; dryness of the mouth and weight loss. They considered 20% of the patients included, as possible psychiatric cases at different measurement points during the study year and argued that patients with oral and pharyngeal tumours are often fragile before the start of treatment to the extent that even minor traumatic experience may be a burden to their psychology (Hammerlid et al. 1998).

De Graeff et al (1998) prospectively assessed 75 oral and oropharyngeal cancer patients for their quality of life change in the 1st year after surgical treatment of the cancers with or without radiotherapy. They used the EORTC cancer core and site specific questionnaires in addition to the Centre for Epidemiologic Studies-Depression Scale at three times during management, preoperative baseline and 6-months and 12-months. They reported a significant drop in physical functioning with most head and neck symptoms at 6-months, which also did not improve significantly much after one year. Surgery and radiotherapy resulted in poorer scores for most physical symptoms at 6 and 12 months compared to patients who received surgery alone. Emotional functioning, although started low at baseline, improved significantly with time, but depressive symptoms remained the same. Also global quality of life did not change after 6 and 12 months, but a trend for improvement was noted (de Graeff et al. 1999).

Schliephake et al (1996) studied prospectively the health related quality of life of oral and pharyngeal cancer patients treated surgically over a period of 12 months. They reported a continuous increase in the Functional Living Index-Cancer (FLIC) scores throughout the 12-months postoperative follow-up period. The increase was mainly in the physical/functional state. However, this increase did not account for one third of the patients who died in the follow-up who started with low QOL scores and showed a gradual decrease during the study (Schliephake et al. 1996).

De Boer et al (1999) in a literature review study reported that head and neck cancer has a strong impact on a patient's quality of life. Common problems are: speech, dry mouth and throat, and swallowing. From the psychological aspect, a considerable number of patients reported worry, anxiety, mood disorder, fatigue and depression. This negatively affected patients' social, recreational and sexual functioning (De Boer et al. 1999).

Deleyiannis et al (1997) compared two groups of patients with stage III or IV oro-pharyngeal cancer: 6-patients treated with surgery and radiotherapy and 7-patients treated with radiotherapy only. They found no difference in the quality of life outcome between the two groups in the UW-QOL. Although, there was no difference in the survival rates between patients, the small number of patients included in the study justify further confirmation of the results obtained in future research (Deleyiannis et al. 1997).

2.1.2.5 Factors affect QOL

It is most likely that patients with advanced disease will be treated more aggressively and will lose large amounts of functionally important tissue, which will result in significant morbidity. Patients with large tumours (stage III+IV) were more affected by their disease at diagnosis than patients with small tumours (stage I+II) and they showed a prolonged period of a worst score (Hammerlid et al. 1998, Rogers et al. 1999d).

Rogers et al (1999), in a study of HRQOL in oral and pharyngeal cancer patients found that men reported a lower QOL at one year, and age made little difference in the QOL outcome, however, elderly patients had a larger drop in the cumulative score of UW-QOL at 3-months and took longer to recover (Rogers et al. 1999d). A cross sectional study of postoperative oral cancer patients reported more functional problems in women and young patients, especially for disfigurement, swallowing, and shoulder disability (Hassanein et al. 2001).

Tumour site has a significant effect on the QOL scores as patients with posterior tumours tend to have lower scores than patients with anterior tumour (Hassanein et al. 2001, Lloyd et al. 2003, Rogers et al. 1999d).

Neck dissection is a necessary procedure with tumour resection in the surgical management of oral and pharyngeal cancer in order to remove lymph nodes in the neck draining the tumour area. Research shows that various forms of neck dissection have a similar impact on quality of life after 1 year of the surgery, except for radical neck dissection (Kuntz et al. 1999). Radical neck dissection (which is not a common procedure now in the U.K.) permanently damages the spinal accessory nerve and significantly affects shoulder function.

Combined therapy of surgery and radiotherapy is a treatment option for large tumours and when there is a potential risk for the cancer to spread to tissues in the neck. Researchers found the combined therapy of surgery and radiotherapy produced the worst scores for most physical symptoms compared to surgery alone (de Graeff et al. 1999, Rogers et al. 1999d).

Researchers suggested that depressive symptoms and mood play a role on the QOL after treatment as a high level of depressive symptoms was reported both before and after treatment in oral and pharyngeal cancer patients (Christensen et al. 1999, de Graeff et al. 2000). A cross sectional study of 68 postoperative oral cancer patients reported anxiety and depression to be strongly associated with poor functional status (Hassanein et al. 2001).

Long-term overall responses to quality of life questionnaires demonstrated that these patients have adjusted to their deficits and have a good life quality; and factors that would be expected to negatively affect QOL, such as appearance, eating ability, respiratory function, shoulder function, actually had minimal effect on the QOL of these patients. However, the authors attributed these results to the good support from family and friends,

the good relationship with the treating physician and the access to a qualified/professional rehabilitation team (Ruhl et al. 1997).

2.1.2.6 Predictors of QOL

Rogers et al (2000) in a study of oral and pharyngeal cancer patients distinguished two groups of patients at baseline based on the cumulative score of the University of Washington Quality of Life Questionnaire (UW-QOL). Patients who scored less favourably at baseline continue to do so in the 1st year following treatment (Rogers et al. 2000). In a different report, Rogers at al (1999) compared the HRQOL domain scores of oral and pharyngeal cancer patients at one-year and long-term survivors (5-10 years). They found comparable HRQOL domain scores between the two groups and suggested that patients' responses at one year following surgery are a useful indicator of the long-term outcome. Nevertheless, the author read this conclusion with caution, because survivors in this study mostly were patients with anterior lesions and received surgical treatment only. This might influence quality of life scores as poorer functional scores have been reported in patients with posterior tumour and those who had adjuvant radiotherapy (Rogers et al. 1999c). A similar results have been reported in a multicentre study for laryngeal cancer patients where they found little changes in patients' HRQOL scores between 1 and 5 years (Nordgren et al. 2003). In the same study there was a strong correlation between HRQOL scores at diagnosis and survival, where patients who died in the 1st year follow-up had much worse scores compared to patients who survived 5 years postoperatively.

De Graeff et al (2000) in a prospective study for head and neck cancer patients' quality of life used the EORTC core and site specific questionnaires and the Centre for Epidemiologic Studies Depression scale (CES-D) on a sample of 153 patients. They found that depressive symptoms and group (a variable incorporating site, stage, and treatment)

and functional score at baseline were major factors predicting QOL after treatment (de Graeff et al. 2000). They also found pre-treatment cognitive functioning measured in the EORTC (+3) were independent prognostic factor for recurrence and survival for patients receiving primary treatment. The performance status, physical functioning, mood and global QOL did not predict recurrence or survival (de Graeff et al. 2001).

2.2 Aims and objectives of the study

The study designed to evaluates the Health Related Quality Of Life (HRQOL) of patients diagnosed with oral and pharyngeal cancer at the maxillofacial unit (MFU). The study aims to examine the hypotheses that patients' postoperative anxiety levels at the MFU are lower than preoperative level. Also, the hypotheses there is no significant difference in the scores of patients' HRQOL domains at the preoperative stage, 6-months stage, 12-months stage and at the 24-months stage

In this chapter we shall describe patients' HRQOL at different stages of treatment using the European Organisation for Research and Treatment of Cancer core questionnaire (EORTC-C30) and Head and Neck specific questionnaire (EORTC QLQ-H&N35), and the Medical Outcome Studies Short Form quality of life questionnaire (SF-36). Also we shall examine the relationship between patients' demographics / tumour characteristics and HRQOL results; and identify variables most significantly correlated with HRQOL domains scores. Moreover, significant correlations between domains from the EORTC-C30 with the SF-36 well be highlighted, and identify HRQOL aspects significantly correlate with (thus predicted by) anxiety scores.

2.3 Material and methods

2.3.1 The study design and patients recruitment

The study protocol was approved by the UCL Research and Development Unit-Ethics committee (see appendix III). The patients' recruitment period extended over one year (6 months recruitment and 6 months follow up) between August 2002 to September 2003, and the inclusion criteria were:

- patients to be competent in speaking and understanding English
- patients age 16 years or more
- patients diagnosed with oral and pharyngeal cancer with no distant metastases
- treatment should be aimed for curative and not palliative
- upon diagnosing a patient with recurrence further data will not be included
- patients should be able physically and mentally to personally complete the questionnaires
- patients should have surgery as the main treatment with or without radiotherapy

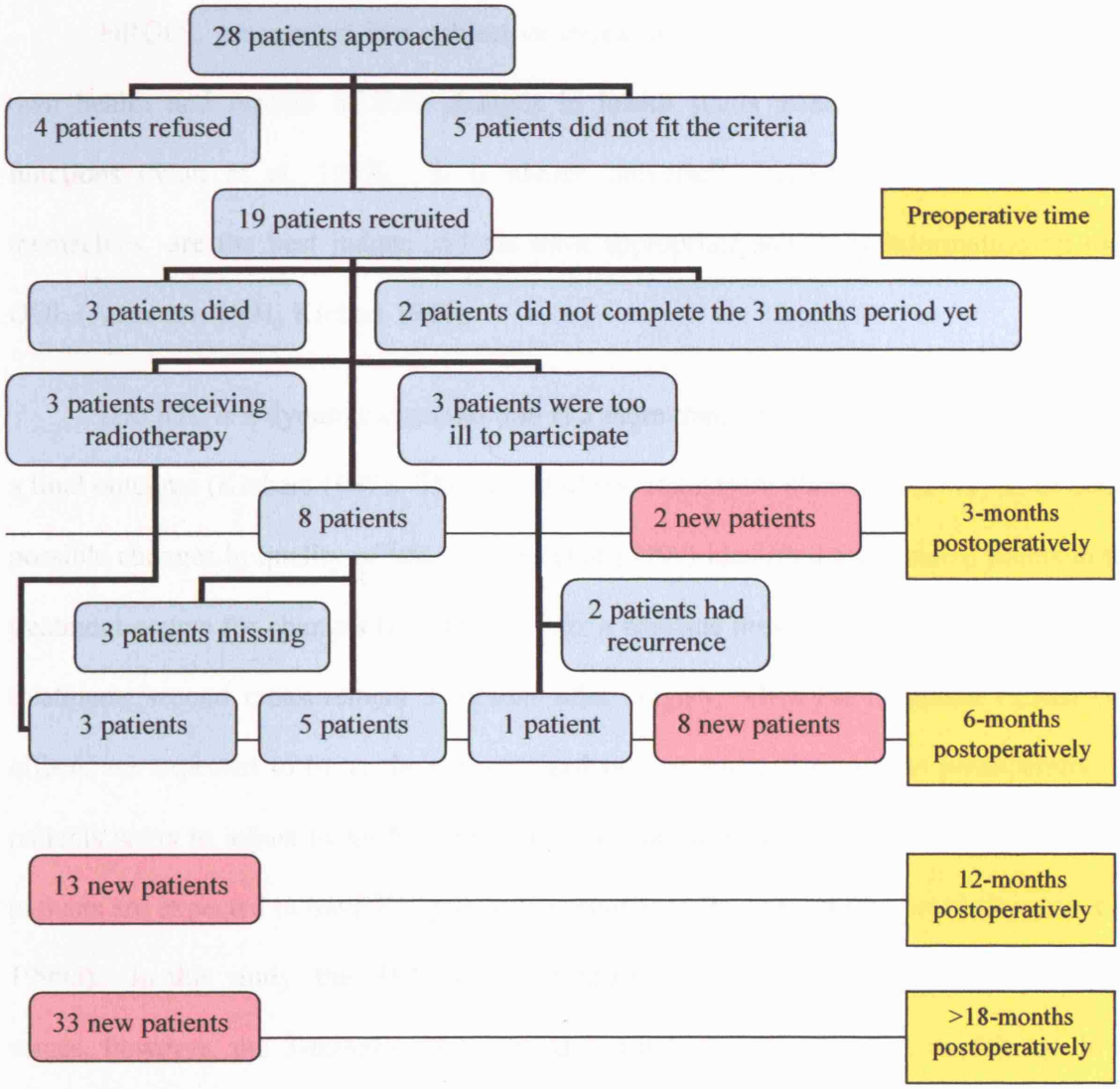
Patients were recruited in a successive independent sampling technique where patients from different times of cancer management recruited to complete the questionnaire once, making a cross sectional survey study. However, patients completed the HRQOL questionnaires at 6-months postoperatively with records preoperatively will be analysed separately (as a longitudinal study) as changes in scores over time can be reported for the same individuals.

There were 19 preoperative patients, 10 patients 3-month postoperatively, 17 patients 6-month postoperatively, 13 patients 12-month postoperatively, and 33 patients 24-month postoperatively. The preoperative cohorts were newly diagnosed oral and

pharyngeal cancer patients attending the unit for treatment. 28 patients were approached, 4 patients refused (psychologically distressed), 5 patients did not fit the criteria, and 19 patients were recruited. The postoperative cohorts were made from 56 oral and pharyngeal cancer patients who had gone through the experience of cancer diagnosis and treatment and continue to attend the clinic as part of the follow-up programme that may extend up to 5 years in the unit (see chart below).

Patients were recruited to the study during their visit to the clinic. In a quiet room patients were given a brief introduction to the study and invited to participate with the knowledge that there is no obligation to participate and can pull out any time from the study without treatment be effected. Patients received a written information sheet and signed a consent form (see appendix III), then a package of all the four questionnaires were given to take home in pre-stamped addressed envelopes to complete and send back to the unit within a week. Preoperative patients completed the questionnaire in the week before the operation as they were instructed to bring the questionnaires along when they were admitted for the operation.

The multi-disciplinary clinic in the maxillofacial unit ran once a week and the two consultant surgeons have two operating days during the week. The setting of the clinic is described in the previous chapter. The study was restricted to using one consultant's clinic, as coordination to see patients by the same researcher in the two consultant clinics running at the same time proved difficult.



The graph illustrates the number and distribution of patients at different time of management. Preoperatively, 19 patients completed the HRQOL questionnaires. At 3-months time, 8 patients from the preoperative cohorts completed the questionnaires and additionally 2 new postoperative patients. At 6-months time, 9 patients from the preoperative cohorts completed the questionnaires and additional 8 new postoperative patients. At 12-months and >18-months times 13 and 33 new patients completed the questionnaires respectively.

2.3.2 The Questionnaires

HRQOL assessment is a subjective evaluation of people's perceptions about their own health and reports of how changes in health status affect performance of usual functions (Wan et al. 1997). It is almost universally accepted today, that patients themselves are the best judges and the most appropriate source of information on their QOL (Aaronson 1991, Kiebert 1997).

HRQOL is a dynamic outcome and is a more transient time-dependent process than a final outcome (Kiebert 1997). The timing of the assessment planned in a way as to detect possible changes in quality of life. Rogers et al (1999) identified four critical points in the treatment course for changes in quality of life: a baseline measurement prior to the start of treatment; second measurement 3 months after surgery, when the treatment related side effects are expected to be at their most; third measurement at 6 months postoperative as patients starts to adjust to his/her new life style; fourth measurement at 12 months where patients are expected to have HRQOL scores similar to the preoperative level (Rogers et al. 1999d). In this study, the HRQOL questionnaires were completed at these 4 common stages, however, the 3-months stage was difficult because many patients felt too ill to participate or missed follow ups during the radiotherapy treatment course.

There is no gold standard with respect to the instruments to measure quality of life. Ideally a QOL questionnaire should be short, concise, and easy to understand. It should depend on patient input only and minimise the opportunity for health-worker bias. The questionnaire should be easy (self-administered), self-explanatory, requiring minimal institutional expense of time and resources, and it should take into account the many aspects of life while being responsive to changes in health (Hassan et al. 1993). The questionnaire should have proven good psychometric properties with respect to validity and

reliability. The HRQOL questionnaires selected in this study satisfy these criteria and been tested before on this group of cohorts. Patients would be screened for anxiety by a separate instrument (the HADS), as anxiety is most likely to be affected by the educational intervention (see appendix X) (Bergelt 2005).

Two basic types of instrument commonly used to describe HRQOL in cancer patients are generic and disease specific. The generic instrument assesses health information that represents the basic components that constitute an individuals' health related quality of life & well being. The proposed target for this type of instrument is a wide range of population and health states. The SF-36 is an example of this type. General health measures provide an overall assessment of patient functioning and well being, allow comparisons across different diseases, and provide a measure to understand side effects and trade offs of different therapies.

Disease specific instruments such as the EORTC QLQ-C30 have been developed especially to detect subtle, disease and/or treatment related effects. Site specific instruments such as the EORTC H&N35 are supplementary to the core questionnaire and provide a more precise measure of disease specific related symptoms and treatment related side effects; and is usually more sensitive to clinical changes.

The unique aspects of head and neck illness are not adequately assessed by general health measures. Equally, patients with head and neck disease demonstrate significant roles in general health status in ways that are not typically reflected in head and neck specific measures. Therefore, a comprehensive assessment of quality of life in head and neck patients requires both general and disease specific instruments (Deleyiannis et al. 1997, Gliklich et al. 1997, Rogers et al. 1998a).

Four questionnaires were used in this study. The questionnaires reported to be acceptable and easy to complete when used individually, however, considerable time and cooperation from the patients agreed to participate was needed to complete all four at the same time. This demands understanding from patients who agree to take part of this study; and also may explain the missing of some items when questionnaires are completed. The questionnaires contents, reliability and validity were discussed in great details in previous studies (Bjordal et al. 2000, Jenkinson et al. 1996, Zigmond et al. 1983).

2.3.2.1 The European Organisation for Research and Treatment of Cancer quality of life questionnaire (EORTC QLQ-C30 ve 3.0 & QLQ-H&N35)

The EORTC quality of life instruments are integrated system for the assessment of health related quality of life for cancer patients. It was released in 1993 by the European Organisation for Research and Treatment of Cancer (EORTC) Study group on Quality of Life. The EORTC QLQ-C30 is a multi-factorial 30 item core questionnaire. It is made up of five functional scales: physical function (5 items); role function (2 items); cognitive function (2 items); emotional function (4 items) and social function (2 items), and three symptom scales: fatigue (3 items); pain (2 items); nausea and vomiting (2 items) along with a general health status (2 items). Additional six single items assess a number of disease related symptoms and financial impact. The cognitive function domain was of special interest for this study as it is central in the process of patient's education.

The EORTC core questionnaire is supplemented with a site specific module the EORTC QLQ-H&N35 which is more precise in assessing the symptoms of the disease and treatment side effects on the patients' daily life and is more sensitive for clinical changes

over time. The module consists of 35 questions assessing symptoms and side effects of treatment, social functioning and body image/sexuality. The seven multiple items scale assesses pain (4 items), swallowing (4 items), senses problems (2 items), speech problems (3 items), trouble with social eating (4 items), trouble with social contact (5 items) and less sexuality (2 items). There are a further eleven single items related to the treatment's side effects.

An average of the items contribute to each scale (the raw score) is calculated and used in a linear transformation equation to standardise it, so that scores range from 0 to 100; a high score represents a higher response level (e.g. high general health status means high QOL or a high symptoms score means a high level of problems)(Quality of life unit 2001).

The EORTC QLQ-C30 and QLQ-H&N35 were well accepted by patients and compliance was high. The time needed for completing both questionnaires is very acceptable (<20 min in 95% of patients). Both questionnaires have a high level of construct validity and excellent reliability. The test-retest reliability of the QLQ-H&N35 seems to be similar with that of the QLQ-C30. The only area where the QLQ-H&N35 failed to show a consistent correlation pattern was in the disease stage. The EORTC QLQ-H&N35 in conjunction with the EORTC QLQ-C30 was regarded by the EORTC group as the standard instrument to measure HRQOL in head and neck cancer patients and it has been used for reporting HRQOL in many studies (Bjordal et al. 2000, Hammerlid et al. 1998, Klug et al. 2002, Rogers et al. 1999c).

2.3.2.2 The Hospital Anxiety and Depression Scale (HADS)

The Hospital Anxiety and Depression Scale is a self administered questionnaire developed by Zigmond and Snaith in 1983. It is written in simple direct questions on one A4 page and takes only 2 to 5 minutes to complete. This makes it quick and simple for use by patients and hospital staff in trial units. The scale was designed to screen medically ill patients for the presence of caseness (possible and probable) of anxiety and depression among non-psychiatric patients in hospital clinics. However, the scale should not be used for diagnostic purposes (Berard 2001, Silverstone 1994).

The scale was divided into an Anxiety subscale (HADS-A) and a Depression subscale (HADS-D). Each subscale is made up of 14 statements relevant to either generalised anxiety or depression (mainly inability to experience pleasure); seven reflecting anxiety and seven reflecting depression. Each item answered will provide a score as indicated by a four point (0-3) response category; so the possible scores ranged from 0 to 21 for anxiety and 0 to 21 for depression. A score of 0 to 7 for either subscale could be regarded as being in normal range, a score of 11 or higher indicated probable presence ('caseness') of a mood disorder and a score of 8 to 10 being just suggestive of the presence of the respective state. A more recent scoring system divide the mood state into four ranges: normal, mild, moderate and sever (Snaith 2003).

The cut-off value 8^{+} (more than 7) defined by Zigmond and Saith for a possible case of psychiatric illness gave the optimal balance between sensitivity and specificity and showed relatively little variability (Bjelland et al. 2002). In this study we adapted this method for considering patients to be in the normal range when they score less than 8, and probable presence of mood disorder when scoring more than 7.

The HADS was validated for assessing severity and caseness of anxiety disorder and depression in both somatic and psychiatric cases in deferent sittings including hospital practice, primary care and general population; and among the elderly and adolescent (Johnston et al. 2000, Snaith 2003). It has good screening properties similar to, but more comprehensive than, instruments used for identification of anxiety disorders and depression (Bjelland et al. 2002). Although single-item QOL indicators (such as HAD) have a higher compliance rate, it may produce less reliable data, have reduced discrimination validity and are less precise for specific treatment effects than multi-item scales (Bernhard et al, 2001).

The HAD scale has been documented in cancer patients screening for psychiatric illness with good validity and reliability (Carroll et al. 1993, Hammerlid et al. 1997). In head and neck cancer populations, the HADS was recommended for getting valid information about the probability of mood disorder. It was well accepted and found to be sensitive to changes in quality of life over a period of time (Hammerlid et al. 1999a).

2.3.2.3 The Medical Outcome Studies-Short Form (SF-36)

The Medical Outcome Study Short Form (SF-36) is a well known generic health profile (multidimensional). It was developed by the RAND Corporation Health Insurance Experiment (HIE) and subsequently by the Medical Outcomes Study (MOS). It is designed with the intention to supplement disease specific measures when used on a sample of patients.

The instrument is a self-administered short 36 items questionnaire: physical functioning (10 items), role limitations due to physical problems (4 items), role limitation due to emotional problems (3 items), social functioning (2 items), mental health (5 items), energy/vitality (4 items), pain (2 items), and general health perception (5 items). The

patient's perception of their health change over the previous year is examined in a further unscaled single item question. For each dimension item scores are coded, summed up and transformed on to a scale from 0 (worst possible health state) to 100 (best possible health state). The British version has a minor modification in the outlay and the wording of six items from the original SF-36 in order to make it more acceptable locally. The developers suggest that the questionnaire take 5-10 minutes to complete by the patients with a good response rate. The instrument reported a good validity and internal reliability in the UK population. The questionnaire is validated internationally in many languages and population norms are available for use in a British context (Jenkinson et al. 1996).

Although the SF-36 questionnaire can produce a summery score for the physical health component (PCS) and mental health component (MCS), the intention of this study was to give detailed descriptions of the HRQOL domains in oral and pharyngeal cancer patients; therefore, domains scores are presented individually as in the other questionnaires.

The SF-36 has been used in cancer patients and reported in surgically treated head and neck oncology patients with good validity and satisfactory internal reliability as well as sensitivity to change over time (Rogers et al. 1998a).

2.3.3 Statistical analysis

Data was entered into the computer using the statistical package SPSS v11. Standard descriptive statistics were used to present the patients characteristics in both the longitudinal and the cross sectional studies. The domains scores will be presented using percentages, means and standard deviation, 95% confidence interval around the mean, and box and whisker plots.

In the cross sectional study, for significant differences between different groups of patients the Chi square test was used for categorical data and the Mann-Whitney test for measurement data. Significant association will be examined by the Chi-square test or Person correlation coefficient where appropriate. In the longitudinal study, the significant difference between the groups will be tested by the Wilcoxon test, and for association the Person correlation test will be used.

The anxiety scores assessed by the HADS will be examined for association with the psychological domains from the EORTC QLQ-C30 and the MOS SF-36. When significant correlation between variables was established, regression analysis was used for the predictability of one variable to another and also for writing the equations.

It is important to note that in the analysis patients at the 12-month stage and 24-month stage are considered as one group. This grouping was made as the literature reports that quality of life scores were similar between the one-year and long-term patients, and it would appear that patients' response at one year following surgery is a useful indicator of the long-term success (Lloyd et al. 2003, Nordgren et al. 2003, Rogers et al. 1999c).

Missing data: missing data scores were estimated from the average scores of answered items for each domain for the individual respondent. For example the raw score was calculated by adding the values of the items in the scale and divided by the number of the items in the scale (i.e. Q1+Q2+...Qn/n); a scale of 4 items with one missing item will have a raw score (Q1+Q2+Q3 /3) and this score will be used in the linear transformation equation for standardisation. This method has been recommended in both the SF-36 and the EORTC QLQ-C30 scoring manuals (see appendix XI and XII) and is indicated for multi item scales whenever at least half the items are completed (Jenkinson et al. 1996,

Quality of life unit 2001). As recommended in the manuals, the domain score is not calculated (cancelled) when the number of answered items is less than 50% of the items for that domain.

2.4 Results

2.4.1 The cross sectional analysis:

There are 92 questionnaire included in this section completed by 75 patients. Patients' distribution at each time is demonstrated in table 2.4.1.1. It is important to note that the patients' characteristics and distributions described here apply to the HADS and the HRQOL questionnaires (SF-36 and EORTC-C30 and QLQ-H&N35).

Table 2.4.1.1: Patients' distribution at specific time of management

	Pre-op	3-months	6-months	12-months	≥18-months
Cross-sectional	19	10	17	13	33

2.4.1.1 Patients Characteristics:

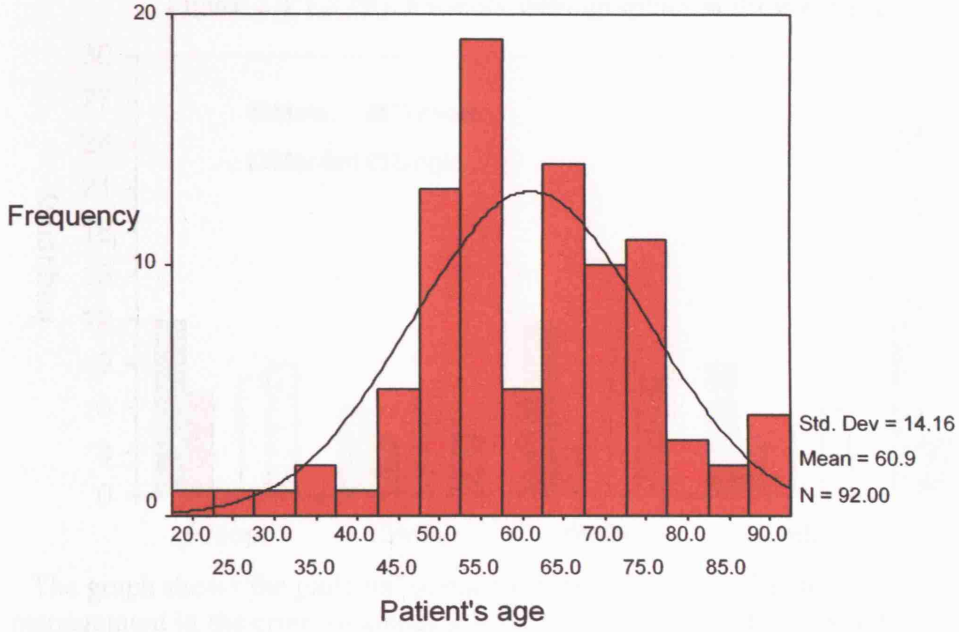
The patients' characteristics are summarised in table 2.4.1.2. The mean age for all the patients involved was 61 (SD: 14) with a range from 22 to 92 years (figure 2.4.1.1). Patients' characteristics at each time are presented in figures 2.4.1.2 (A) – 2.4.1.2 (E).

Table 2.4.1.2: Patients' description at different times of management

		Pre-op	3months	6months	12months	≥18months
Patients No.		19	10	17	13	33
Patients age	Mean (SD)	61(15)	57(13)	63.5(14)	60(14)	61(15)
	Median	57	53.5	63	63	62
Patients gender	Male	12	6	12	9	27
	Female	7	4	5	4	6
Marital status	Married	8	5	9	5	19
	Single	9	4	8	6	11
Diagnosis	†C.tissue	1	1	0	2	2
	††SCC	18	9	17	11	31
Tumour size	T1 & T2	4	2	7	4	21
	T3 & T4	12	5	10	8	10
Lymph node involvement	Negative	11	6	10	8	23
	Positive	7	4	7	5	9
Bone resection	No/marginal		8	14	10	27
	Complete		2	3	3	6
Relation of soft tissue resection to teeth	Ant. or lat.		3	3	6	12
	Post. or med.		7	14	7	21
Neck dissection	I-III		6	12	9	19
	IV-V		4	5	4	14
Reconstruction	Vascular flap		9	16	10	20
	Non vascular		1	1	2	13
Radiotherapy	Yes		4	10	9	19
	No		6	7	4	14

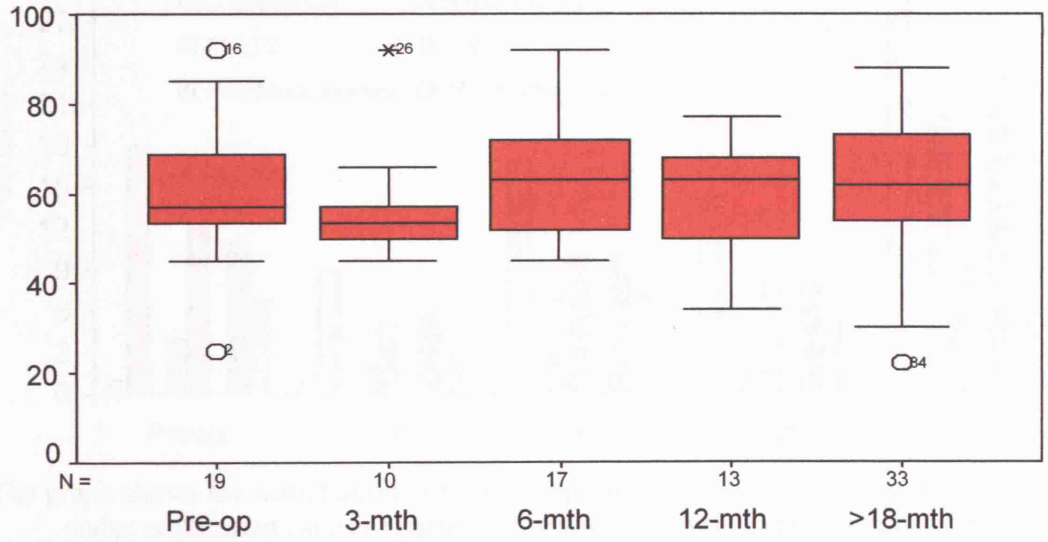
†Connective tissue tumour, †† Squamous cell carcinoma

Figure 2.4.1.1: Patients' age (cross sectional study)



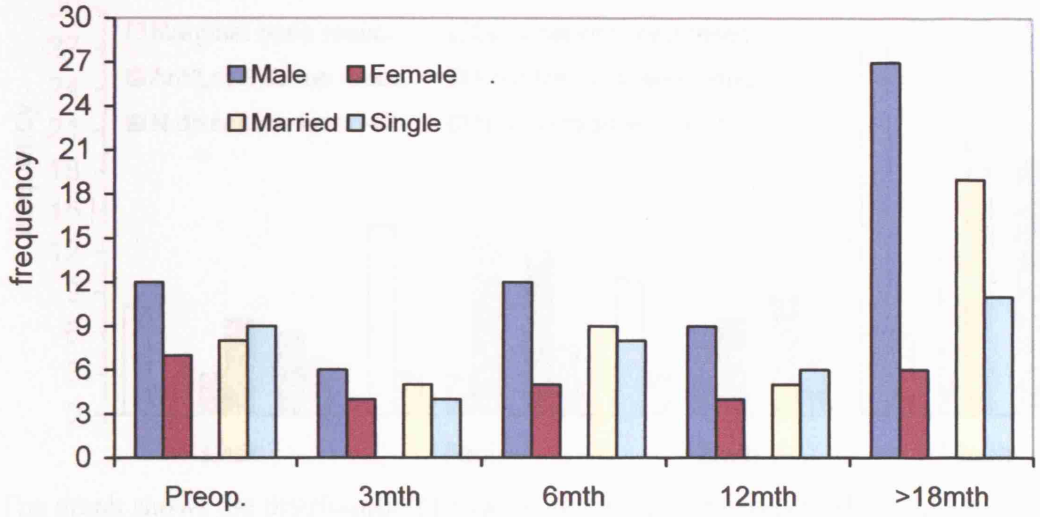
The graph illustrates the normal distribution of patients' age around a mean age of 61 years. The sample included all the patients in the cross sectional study

Figure 2.4.1.2 (A): Patients' age at different stages



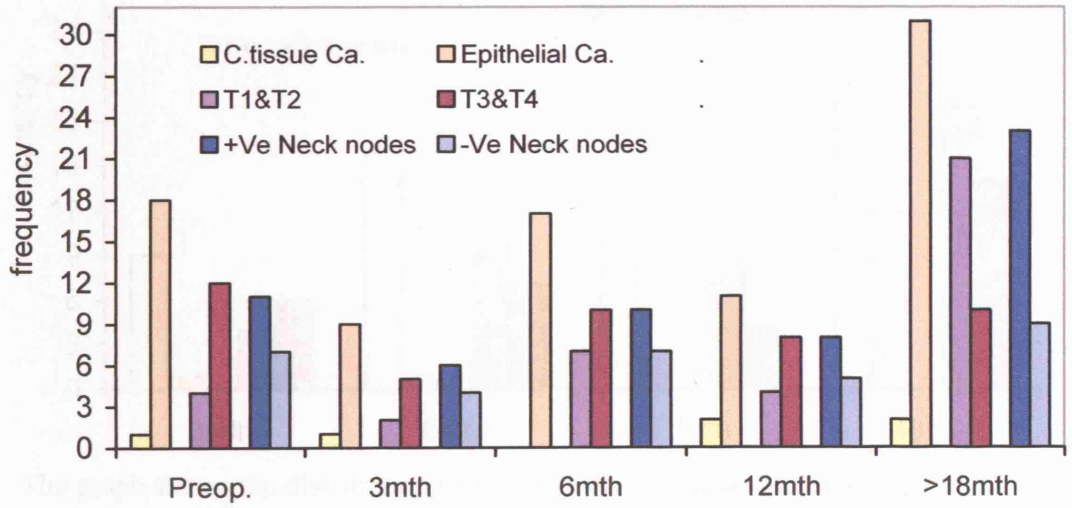
The graph illustrate the age ranges and the median ages for patients at different stages of management

Figure 2.4.1.2 (B): Patients' demographics at different stages



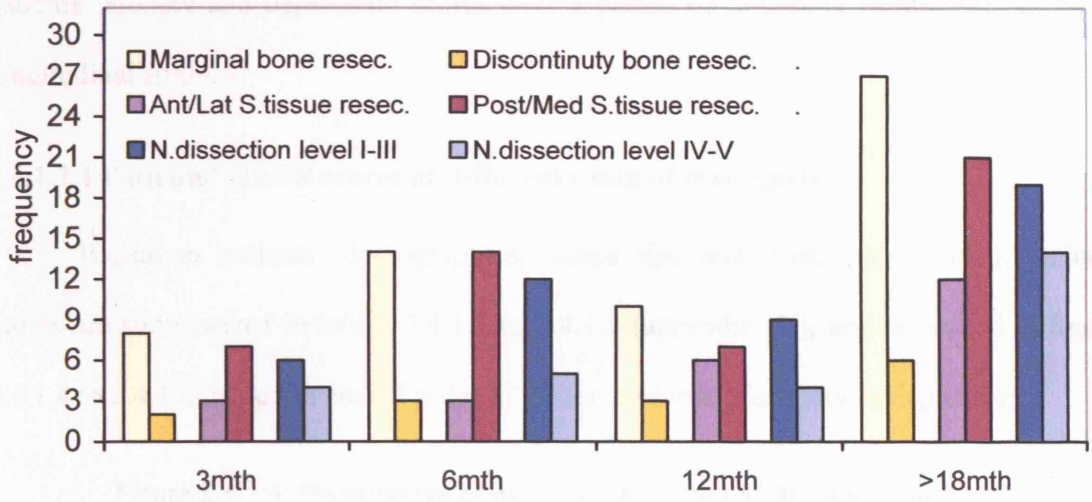
The graph shows the patients' gender and marital status distribution at different times of management in the cross sectional study. Male patients out numbered female patients at all times

Figure 2.4.1.2 (C): Patients' demographics at different stages



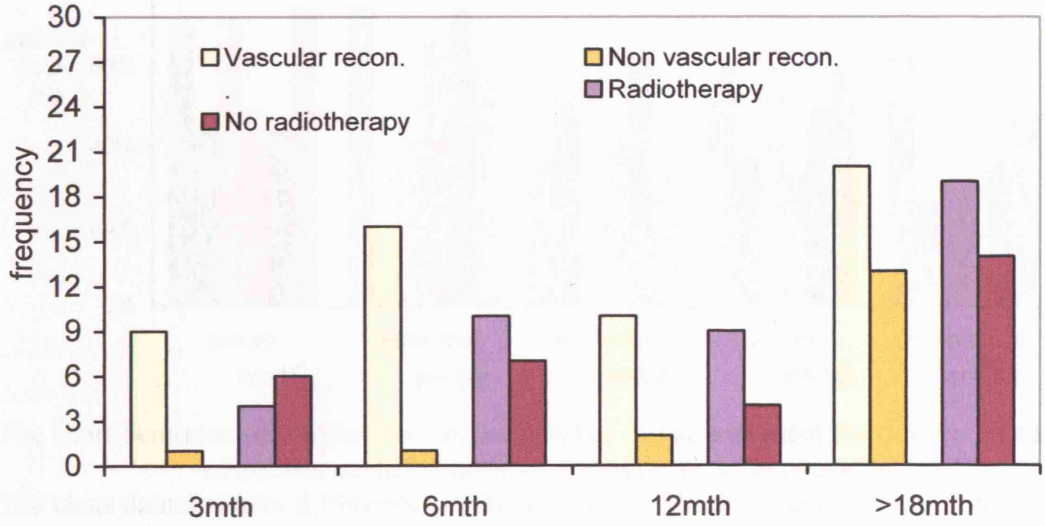
The graph shows the distribution of tumour type and size as well as the state of the neck nodes at different times of patients management in the cross sectional study.

Figure 2.4.1.2 (D): Patients' demographics at different stages



The graph shows the distribution of treatments that patients received for different times of management in the cross sectional study.

Figure 2.4.1.2 (E): Patients' demographics at different stages



The graph shows the distribution of reconstruction type and radiotherapy treatment for different times of management in the cross sectional study.

2.4.1.2 HADS scores

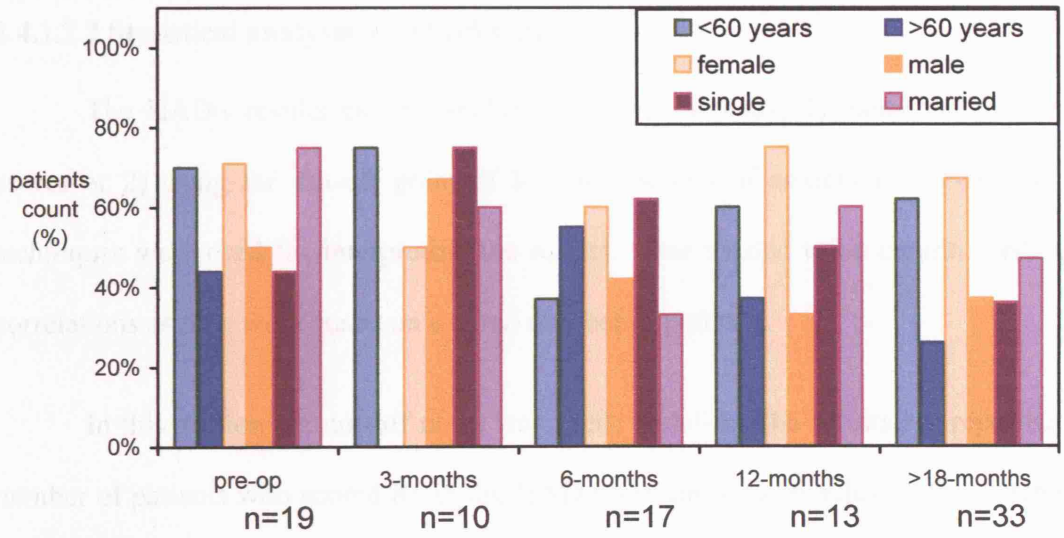
The study aimed to examine the hypotheses that anxiety levels in oral and pharyngeal cancer patients decreases postoperatively with time and that high anxiety levels before the operation predict high anxiety levels after the surgery. Patients were screened

for anxiety and depression at different times in the cross sectional study; and changes in patients' anxiety and depression scores over a period of 6-months were described in the longitudinal study.

2.4.1.2.1 Patients' HADS scores at different times of management:

Based on patients' demographics, tumor size and treatment received; patients' scores are summarized in tables 2.4.1.3 to 2.4.1.7 (appendix IV), and presented in figures 2.4.1.4 to 2.4.1.6 using the cut off point of 8+ for caseness of anxiety or depression.

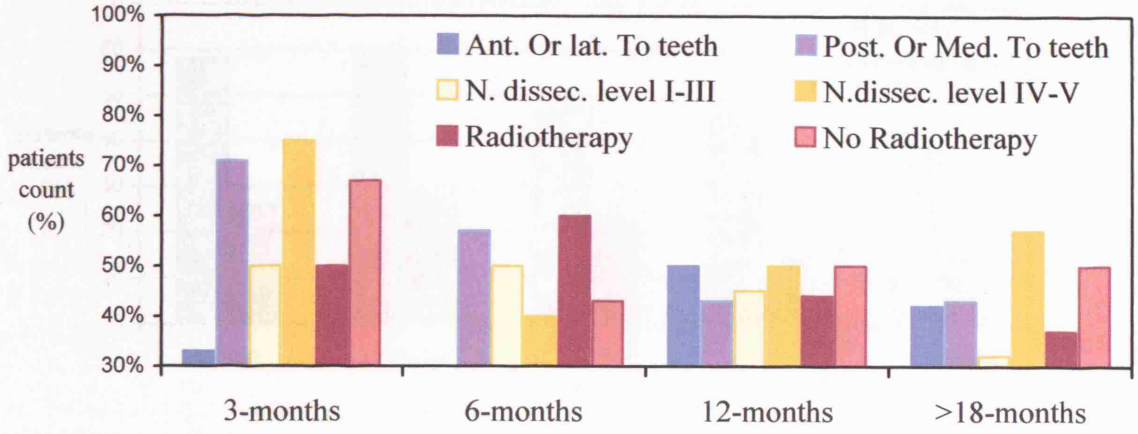
Figure 2.4.1.4: Percentages of patients that scored 8+ for anxiety at different stages based on patients demographics



The chart demonstrates differences in the number of patients meet the criteria for caseness of anxiety at different times based on their demographics

The chart demonstrates differences in the number of patients meet the criteria for caseness of anxiety at different times based on their tumour characteristics

Figure 2.4.1.6: Percentages of patients that scored 8+ for anxiety at different stages based on treatment



The chart demonstrates differences in the number of patients meet the criteria for caseness of anxiety at different times based on treatment received

2.4.1.2.2 Statistical analysis of HADS scores

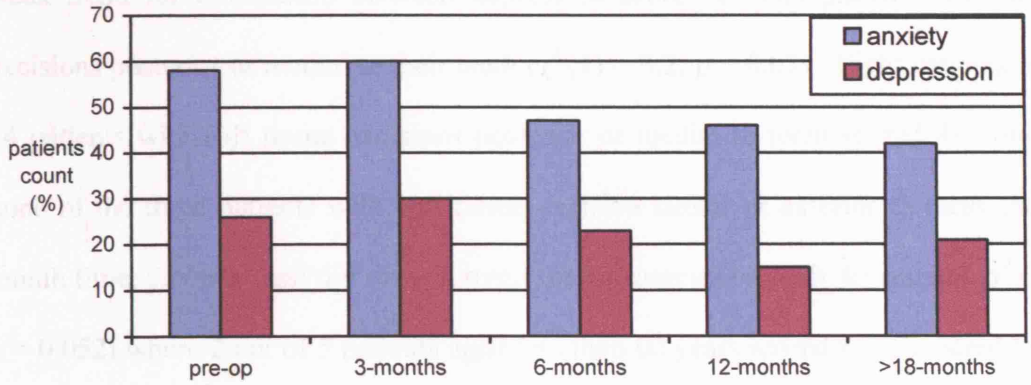
The HADS results can be analysed by two methods; 1) using the patients' raw scores or 2) using the cut-off point of 8+ for caseness of anxiety or depression. Both techniques were used for interpreting the results. One needed to be careful reading these correlations as they were based on a small number of patients.

In this section the cut-off point was used; therefore, the results are reported by the number of patients who scored 8+ in the HAD scale and will be adjusted for differences in the number of patients by reporting patients' number in a percentage. Results are summarised in table 2.4.1.8, and demonstrated in figure 2.4.1.7.

Table 2.4.1.8: HADS scores at different times (cut-off point)

Management time	Number of patients	Anxiety		Depression	
		<8 (%)	8+ (%)	<8 (%)	8+ (%)
Preoperative	19	8(42)	11(58)	14(74)	5(26)
3 months	10	4(40)	6(60)	7(70)	3(30)
6 months	17	9(53)	8(47)	13(77)	4(23)
12 months	13	7(54)	6(46)	11(85)	2(15)
≥18 months	33	19(58)	14(42)	26(79)	7(21)

Figure 2.4.1.7: Differences in percentages of patients that scored 8+ at different stages



To test for a significant association between the caseness for anxiety and patients demographics the Chi-square test was carried out. At the preoperative time, there was a statistically weak trend for association between large tumours (T_3&T_4) and anxiety scores 8+ ($\chi^2(1) = 3.2$; $p = 0.07$), 9 out of 12 patients with T_3&T_4 scored 8+ in the HADS compared to 1 out of 4 patients with T_1&T_2 cancers. At three months post-operatively, there was also a trend for anxiety to be associated with age (χ^2 (1) = 3.8; p = 0.053); 6 out of 8 patients aged less than 60 years scored 8+ in the anxiety scale compared to 0 out of 2 patients aged more than 60 years. This age significance was evident again in the long term follow up patients (>18-months) where 9 out of 14 patients under the age of 60 years reported an anxiety score of 8+ compared to 5 out of 19 patients aged more than 60 years (χ^2 (1) = 4.8; p = 0.03). At the 6-month time, there was a trend for an association between the anxiety 8+ scores and patients with soft tissue excisions posterior or medial to the teeth (χ^2 (1) = 3.2; p = 0.07). There were 8 out of 14 patients with soft tissue excisions posterior or medial to teeth that scored 8+ compared to none of the three patients with soft tissue excision lateral or anterior to teeth.

For depression, in the preoperative time, gender was found to be significantly associated with depression scores (χ^2 (1) = 3.96; P = .047) where 5 out of 12 male patients

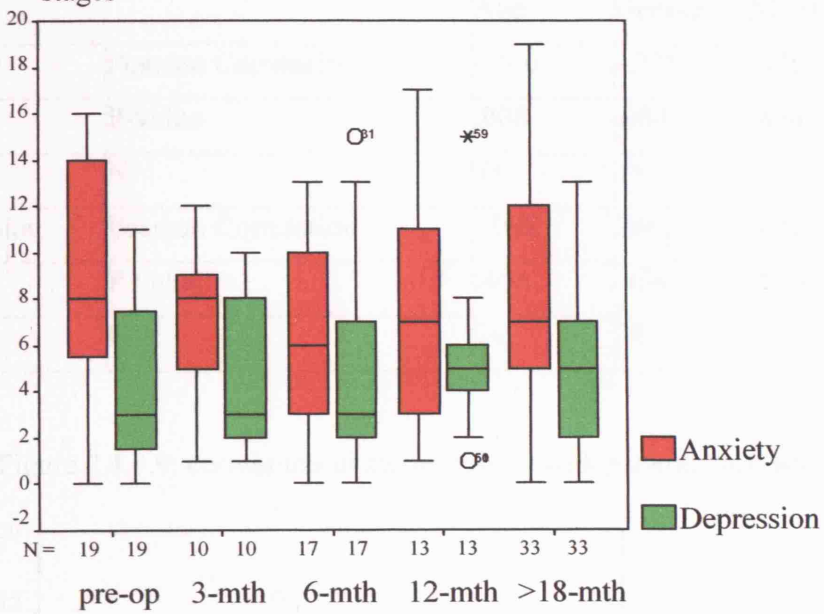
scored 8+ compared to none of the 7 female patients. At the 6-month time, there was a weak trend for association between depression scores 8+ and patients with soft tissue excisions posterior or medial to their teeth (χ^2 (1) = 3.2; p = 0.07). Eight patients out of the 14 patients with soft tissue excisions posterior or medial to teeth scored 8+ compared to none of the three patients with soft tissue excision lateral or anterior to teeth. At the 12-month time, patients' age did show a trend for an association with depression (χ^2 (1) = 3.8; p = 0.052) where 2 out of 5 patients aged less than 60 years scored 8+ compared to none of the 8 patients aged more than 60 years. At the 24-month time, the amount of bone removed showed a trend for an association with depression (χ^2 (1) = 3.64; p = 0.057) where 3 out of 6 patients with loss of continuity bone resection scored 8+ compared to 4 out of 27 patients with no or only rim resection.

In the following analysis the patients' raw scores in the HADS were used. The patients' mean and median scores for anxiety and depression at different times are summarised in table 2.4.9 and demonstrated in figure 2.4.1.8.

Table 2.4.1.9: Patients' scores in the HADS at different times (raw scores)

Management time	Anxiety		Depression	
	Mean(SD)	Median	Mean(SD)	Median
Preoperative	9(5)	8	4(4)	3
3 months	7(4)	8	5(3)	3
6 months	7(4)	6	5(4)	3
12 months	7(5)	7	5(4)	5
≥18 months	7(5)	7	5(3)	5

Figure 2.4.1.8: HADS scores at different stages



The graph shows the differences in patients' median scores for anxiety and depression between different times of management.

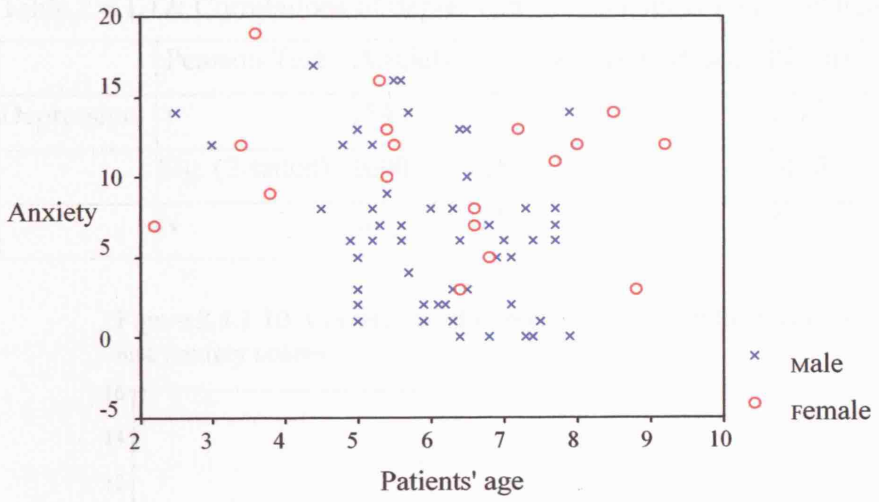
For significant differences in the median scores between the different times the Kruskal Wallis Test was carried out. However, there was no significant difference in the median score of anxiety or depression between the different times ($\chi^2(4) = 2.7$; $p = 0.61$).

For a significant association of patients' characteristics with anxiety or depression, the Pearson correlation test was carried out. In this test, patients were included only once, therefore the data is filtered to include one score for each patient, also an attempt to have an equal number of patients in the first three times where duplications occurred. Figure 2.4.1.9 demonstrates a significant negative association between the patients' ages and anxiety where younger patients tended to have higher scores of anxiety in the HADS. Also, a trend for association is noticed between gender and anxiety where female patients tended to have higher anxiety scores than male patients (table 2.4.1.10). Depression scores did not associate with any of the patients' demographics.

Table 2.4.1.10: HADS scores correlation with patients' demographics

		Age	Gender	M. Status	T. Size
Anxiety	Pearson Correlation	-.306	-.225	.026	.017
	P-value	**.008**	**.054**	.834	.892
	N	74	74	66	67
Depression	Pearson Correlation	-.098	.092	.082	.160
	P-value	.406	.434	.514	.195
	N	74	74	66	67

Figure 2.4.1.9: correlation of anxiety score with patients' age and gender



The scatter plot graph shows the negative association between anxiety scores and patients' age. This pattern was clearer in male patients.

Regression analysis was carried out to test for the factors (age, gender and time of management) most significantly related (hence can predict) anxiety. Age and gender were found to be a significant predictors for anxiety (F = 4.18; P = .009) (appendix VIII - table 2.4.1.11).

- Predicted anxiety score = 18.19 – (0.005 x Time††) - (0.11 x Age) – (2.51 x Gender†)

† Female = 1; Male = 2

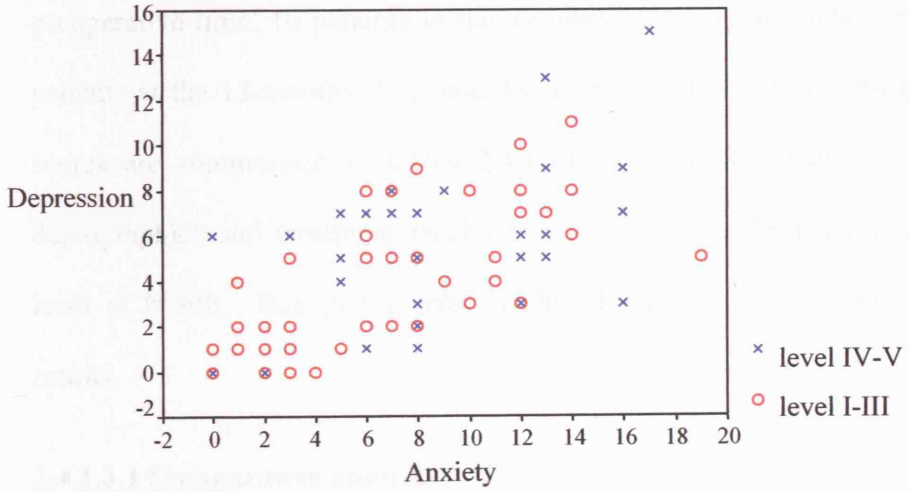
†† Pre-op = 1; 3-months = 2; 6-months = 3; 12-months = 4; >18-months = 5

As depression scores increased during the postoperative period, it was of interest to test for factors significantly associated with changes in depression scores. The Pearson correlation test was carried out for association between treatments received variables including anxiety and postoperative patients' depression scores. As this was analysis for treatment received, only postoperative patients were included here; and for patients who completed the scale more than once (i.e. at 3 and 6 months) only the result from the first test was included. From table 2.4.1.12, anxiety and level of neck dissection were significantly correlated with depression (figure 2.4.1.10).

Table 2.4.1.12: Correlations of depression scores with anxiety and treatment received

	Pearson Test	Anxiety	B. Resec.	S.T. Resec.	N. Dissect.	Recon.	Radioth.
Depression	r	.544	.172	.196	.272	.130	.107
	Sig. (2-tailed)	**.000**	.163	.111	**.026**	.295	.387
	N	67	67	67	67	67	67

Figure 2.4.1.10: Correlation of depression scores with level of neck dissection and anxiety scores



The scatter plot graph shows the strong positive association of anxiety scores with depression scores. This was clearer in patients with level I-III of neck dissection.

Regression analysis was carried out to test for which variables (anxiety, level of neck dissection and time of management) significantly associated with depression. Anxiety

was the most significant predictor for depression (F = 10.314; p = .000) (appendix VIII - table 2.4.1.13).

- Predicted depression score = 0.92 + (0.40 x Anxiety score) + (1.29 x Level of neck dissection†) – (0.16 x Time††)

(† I – III = 1; IV – V = 2) (†† 3-months = 1; 6-months = 2; 12-months = 3; >18-months = 4)

2.4.1.3 The SF-36 questionnaire

The study aimed to examine the hypothesis that there is no significant difference in the scores of patients' HRQOL domains measured in the SF-36 at the preoperative time, 6-months time, 12-months time and at the >18-months time. Previous research used the same questionnaires at different times of management reported that patients regain their preoperative HRQOL levels after one year and there is not much change thereafter in long term survivors (Hammerlid et al. 2001a, Rogers et al. 1999c).

As described previously, each time had a different number of patients; 19 patients at preoperative time, 10 patients in the 3-months time, 17 patients in the 6-months time, 13 patients at the 12-months time, and 33 patients in the >18-months time. Patients' SF-36 scores are summarised in tables 2.4.1.14 to 2.4.1.18 (appendix V) according to their demographics and treatment received. High scores reflect a comfortable or favourable level of health. Box plot graphs in plate-1 (appendix VI) demonstrate individual time results.

2.4.1.3.1 Comparative analysis

The SF-36 domains do change over time after operation; a summary of the mean and median scores at different times are presented in table 2.4.1.19, and demonstrated in figures 2.4.1.15 (A, B, C) with comparison to the Rogers study (1999) and to normal values

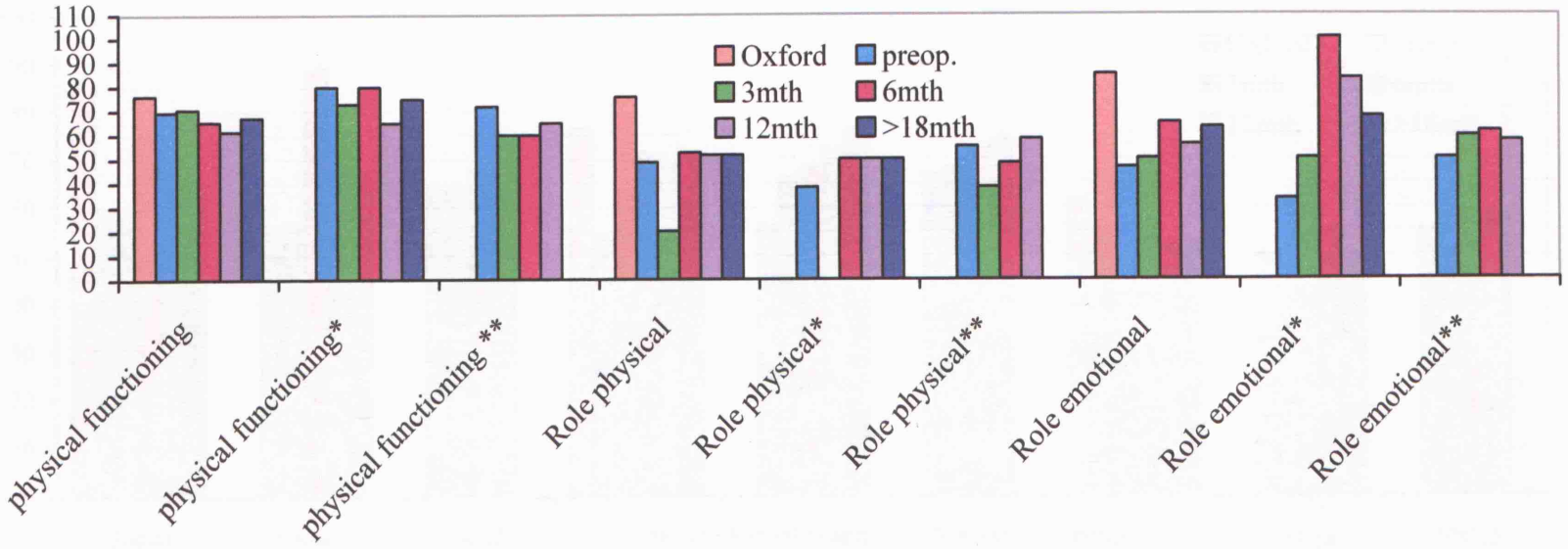
from the Oxford study for the same age range. The differences between the median scores at preoperative time, and at one year or more are demonstrated in figure 2.4.1.16 (A).

Table 2.4.1.19: SF-36 scores compared to data from the Oxford study

	Pre-op time 61 (25-92)*		3-mth time 57(45-92)*		6-mth time 63 (45-92)*		12-mth time 60 (34-77)*		>18-mth time 61 (22-88)*		Oxford (60-64)
	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)
Physical functioning	69.4 (28.1)	80.0	70.5 (25.3)	72.5	65.4 (30.9)	80.0	61.5 (32.4)	65.0	67.3 (29.2)	75.0	76.2 (22.3)
Role physical	48.6 (46.6)	37.5	20.0 (32.9)	.00	52.6 (42.7)	50.0	51.6 (45.3)	50.0	51.6 (42.3)	50.0	75.9 (37.5)
Role emotional	46.3 (47.3)	33.3	50.0 (47.8)	50.0	64.7 (43.3)	100	55.6 (49.9)	83.3	62.1 (42.5)	66.7	84.8 (30.6)
Social functioning	59.9 (27.5)	55.6	57.8 (21.5)	55.6	74.5 (31.4)	88.9	63.2 (31.3)	66.7	65.0 (28.5)	66.7	86.2 (22.7)
Mental health	54.1 (22.4)	56.0	63.6 (10.6)	66.0	71.1 (17.2)	68.0	68.9 (20.4)	72.0	71.2 (21.7)	76.0	76.4 (18.4)
Energy / Vitality	55.3 (23.1)	50.0	41.5 (17.7)	45.0	57.0 (18.8)	60.0	51.9 (23.7)	55.0	52.3 (23.1)	50.0	61.8 (21.2)
Pain	64.3 (27.1)	66.7	53.3 (22.1)	55.6	72.6 (24.6)	77.8	71.8 (24.7)	77.8	65.3 (30.1)	66.7	76.9 (24.0)
General health	59.2 (25.1)	58.5	59.7 (25.0)	57.0	62.7 (24.8)	67.0	54.9 (27.2)	42.0	50.9 (28.8)	45.0	68.1 (21.9)

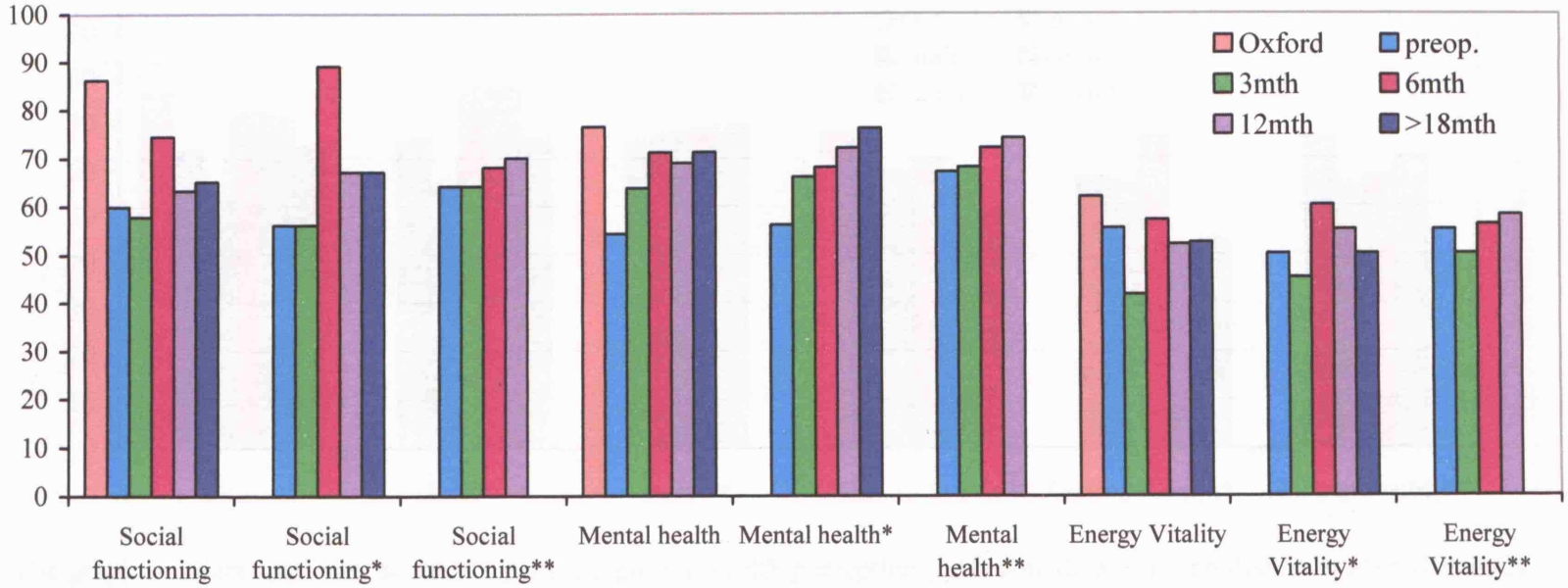
* mean age (range)

Figure 2.4.1.15(A): SF-36 mean scores compared to the Oxford study
(*median,** mean scores from S. Rogers study 1999)



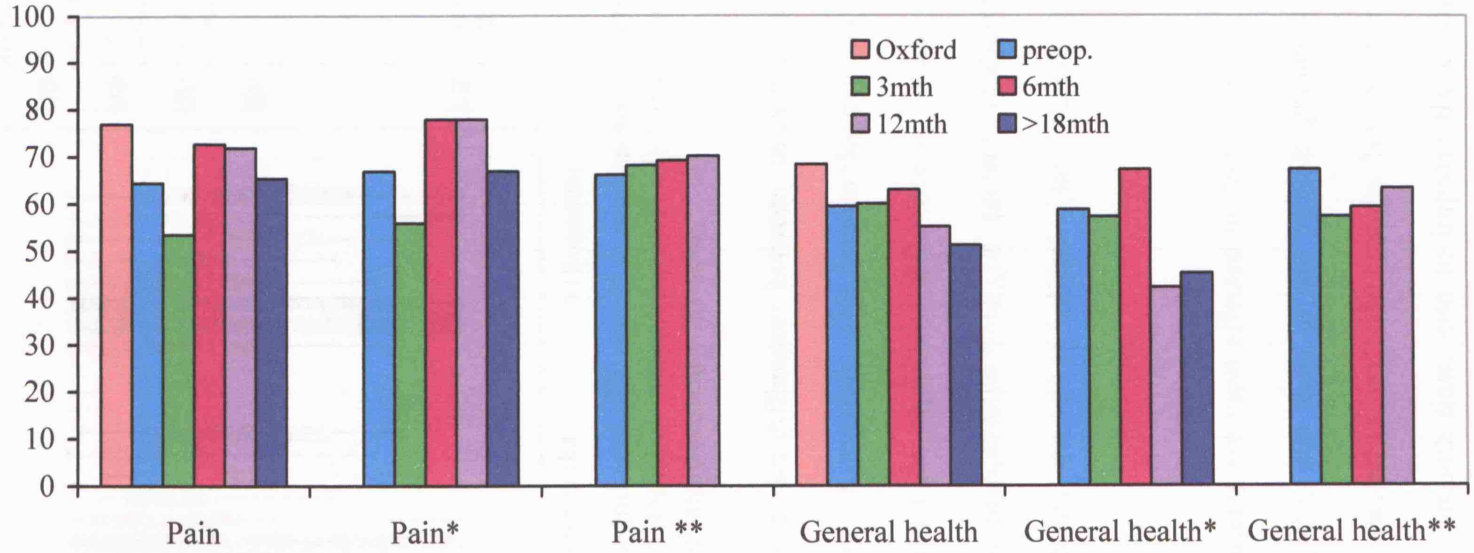
The graph compares patients' scores for physical functioning (PF), role limitation due to physical functioning (RP) and role limitation due to emotional functioning (RE) with data from Rogers at al study (1999) and norms for the same age range from the Oxford study. Although patients regained preoperative scores there are marked differences in RP and RE from norms before and after the surgery. Also there is a marked difference in patients' scores for RP and RE and norms from the Oxford study preoperatively and postoperatively.

Figure 2.4.1.15(B): SF-36 mean scores compared to data from the Oxford study
(*median score, ** mean scores from S. Rogers study 1999)



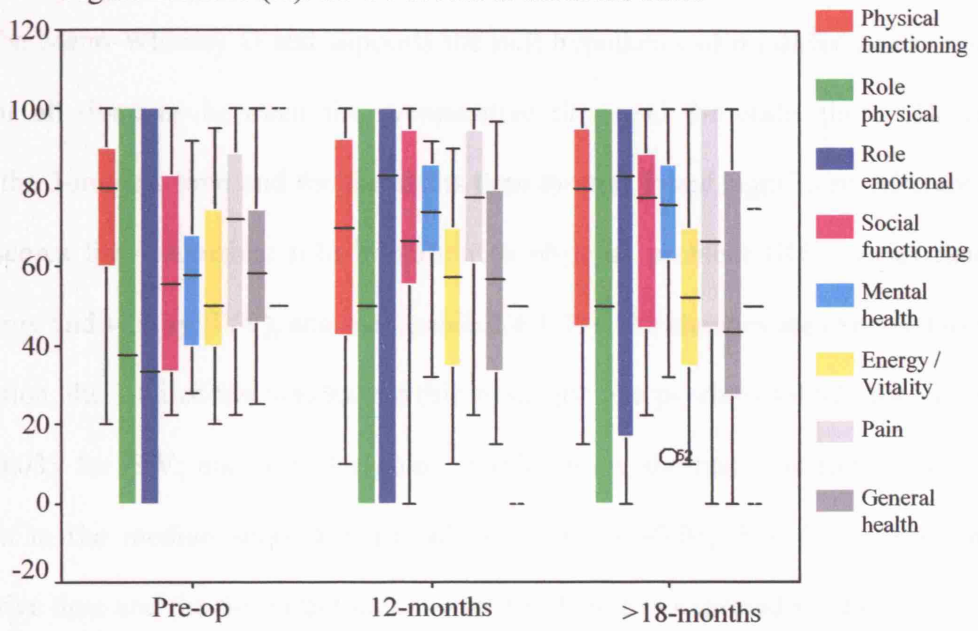
The graph compares patients' scores for social functioning (SF), mental health (MH), and energy and vitality (EV) with data from Rogers et al study (1999) and norms for the same age range from the Oxford study. Social functioning scores are markedly lower than norms pre and postoperatively; mental health, although lower than norms preoperatively, it approach norms level 6-months postoperatively. Energy and vitality postoperative scores gradually approach preoperative level.

Figure 2.4.1.15(C): SF-36 mean scores compared to data from the Oxford study
(*median score, ** mean scores from S. Rogers study 1999)



The graph compares patients' scores for pain and general health perception (GH) with data from the Rogers et al (1999) study and norms for the same age range from the Oxford study. Scores for both domains peak at 6-months then decreases after to similar preoperative level (pain) or lower (GH), however both are lower than norms levels.

Figure 2.4.1.16 (A): SF-36 scores at different times



The box plot graph demonstrates insignificant differences in median scores between different stages for each of the SF-36 domains. Mental health (MH) shows tendency for significant improvement with time.

The Kruskal-Wallis test for significant differences between times was carried out, but it failed to reject the H_0 for all the SF-36 domains. This implies that patients at the 12-month time and >18-month time do not have significant difference in median scores of HRQOL domains from patients at the preoperative time (i.e. patients readjusted to the preoperative level). However, mental health showed an indication for a significant positive change with time (χ^2 (2) = 7.07; p = .029).

Oral and Pharyngeal cancer patients are most affected by the combined treatment (surgery and radiotherapy) after 3-months and most of the patients gradually improve thereafter. Psychosocial support is expected to moderate changes between the patients' preoperative scores and scores at the 3-month time, also to improve the change in the

patients' scores between the 3-month and the 6-months times. The patients' SF-36 scores at these three times are demonstrated in figure 2.4.1.16-B.

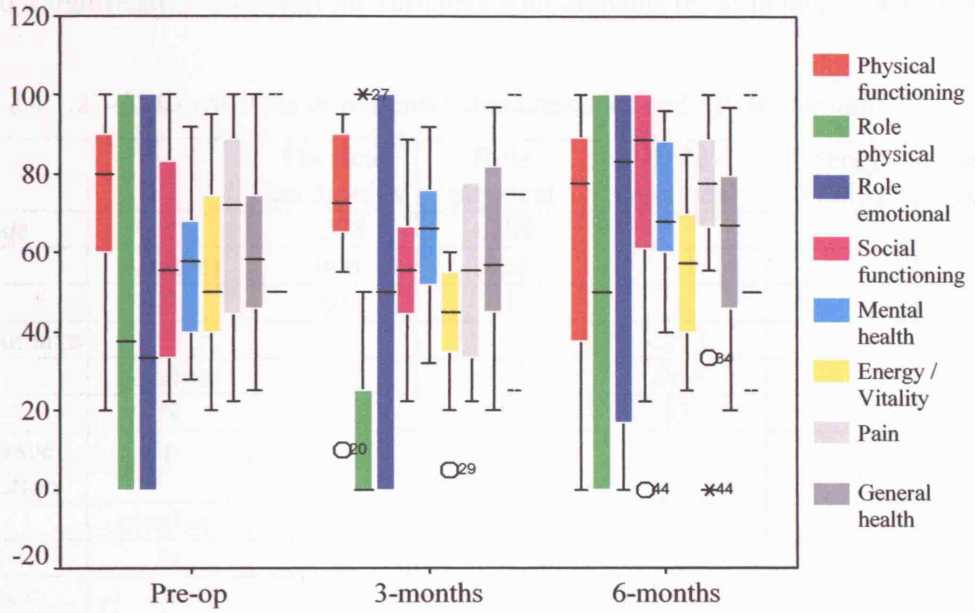
The Mann-Whitney U test supports the null hypothesis of no difference in median scores for all domains between the preoperative time and 3-months time. However, between the 3-months time and the 6-months time the test found significant differences in median scores for 4-domains: role limitation to physical problem (RP), social function (SF), energy and vitality (E/V), and pain (table 2.4.1.20). As changes are expected to be in one direction, the 1-tailed test was halved this value giving a p-value of 0.025 for RP; 0.025 for SF; 0.033 for E/V; and 0.01 for pain. Furthermore, the test indicated a significant difference in the median score for mental health (Z = -0.04; P = 0.04) between the preoperative time and the 6-month time; and as the change is expected in one direction the 1-tailed test halved this value giving a p-value of 0.02.

The Mann-Whitney U test was used to test for significant differences between the patients' scores at the 6-month time and the 12-month time; however, the test was not significant for all domains.

Table 2.4.1.20: SF-36 domains with significant difference between 3 and 6 months

	Role limitation due to physical problems	Social function	Energy/Vitality	Pain
Mann-Whitney U	48.000	46.500	48.500	39.000
Wilcoxon W	103.000	101.500	103.500	94.000
Z	-1.944	-1.962	-1.838	-2.348
P-value	.052	.050	.066	.019

Figure 2.4.1.16 (B): SF-36 score at different stages



The box plot illustrates the differences in patients' median scores between different stages for each of the SF-36 domains. Role emotional (RP), social functioning, (SF), energy and vitality (E/V) and pain showed a tendency for significant improvements between 3 and 6-months.

2.4.1.3.2 Correlation analysis

For regression analysis, most authors recommend that one should have at least 10 to 20 times as many observations (cases, respondents) as one has variables. Because we are going to test 4 preoperative variables and 4 postoperative variables we need to have a number of patients between 40 and 50 patients to do the multiple regression analysis. Therefore, the sample in this correlation analysis will be patients in the preoperative time (19 patients), the 12-month time (13 patients) and the >18-month time (patients 33) for demographic association; for treatment received factors only the postoperative patients will be included. The result in the previous section from the Kruskal-Wallis test and previous reports in the literature, supports that patients have comparable HRQOL domains' score at

the preoperative time, 12-month and >18-month times. The Pearson correlation test showed a significant association for variables with domains listed in table 2.4.1.21-A.

Table 2.4.1.21-A: Correlation of patients' characteristics and SF-36 domains

		Physical functioning	Role physical	Role emotional	Energy/ Vitality	General health
Age	r	-.338	-.289			
	p-value)	.006	.024			
	N	64	61			
Tumour size	r			-.292		
	p-value)			.034		
	N			53		
S. tissue resection	r					-.361
	p-value)					.014
	N					46
Neck dissection	r				-.322	-.341
	p-value)				.029	.020
	N				46	46
Radiotherapy	r			-.386		
	p-value)			.013		
	N			41		

Preoperative predictors are patient's age, gender, and tumour size and neck state. Predictability of these variables to SF-36 domains has been assessed by multiple regression analysis. Increased age significantly predicted worse scores for physical functioning; also, increased age and positive neck nodes independently predicted worse scores for role limitation due to physical problems (appendix VIII - table 2.4.1.21-B). Treatment predictors are discontinuity bone resection, anterior/lateral or posterior/medial to teeth soft tissue resection, level of neck dissection and radiotherapy. None of the SF-36 domains were significantly predicted by treatment predictors in multiple regression analysis.

- Predicted physical functioning score = 164.36 – (1.13 x Patient age) – (11.77 x Gender†) – (0.53 x Tumor size††) – (15.67 x Neck node status†††)

- Predicted role physical score = 135.21 + (4.05 x Gender†) + (0.008 x Tumor size††) – (1.32 x patient age) – (31.53 x Neck node status†††)

† Female = 1 and Male = 2; †† T_1&T_2 = 1 and T_3 & T_4 = 2; -Ve neck = 1 and +Ve neck = 2

2.4.1.4 The EORTC-C30 questionnaire

The study aimed to examine the hypothesis that there is no significant difference in the scores of patients' HRQOL domains measured in the EORTC-C30 at the preoperative time, 6-months time, 12-months time and at the >18-months time.

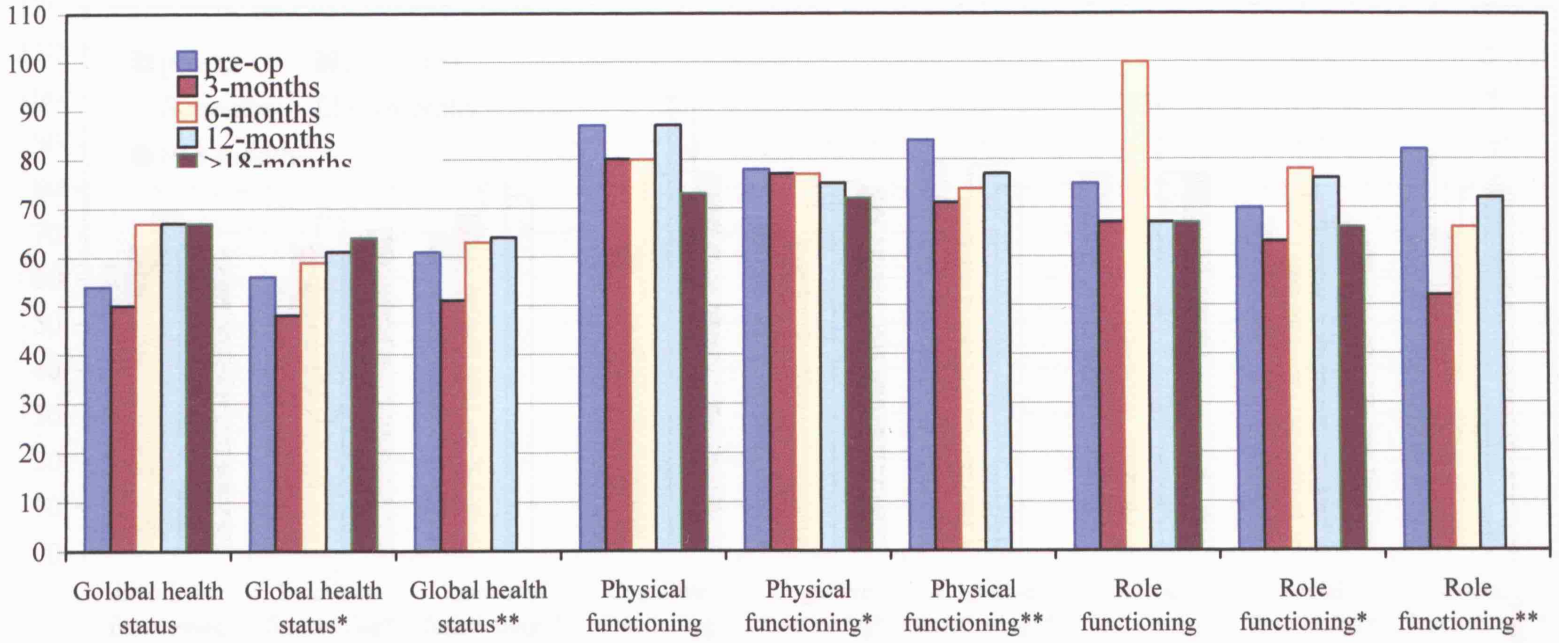
As described previously, the cross sectional analysis examined patients' HRQOL at 5 different times of management. Each time had a different number of patients; 19 patients at the preoperative time, 10 patients in the 3-months time, 17 patients in the 6-months time, 13 patients at the 12-months time, and 33 patients in the >18-months time.

The patients scores at each time are summarized in table 2.4.1.22, and demonstrated in figures 2.4.1.17 (A, B, C, D), and are compared with a previous study (Hammerlid et al. 1997). High functional scores represent a healthy level of functioning, high symptom scores indicate high levels of symptomatology/problems, and high global health status indicates a better QOL.

Table 2.4.1.22: Summary of EORTC-C30 scores at different times

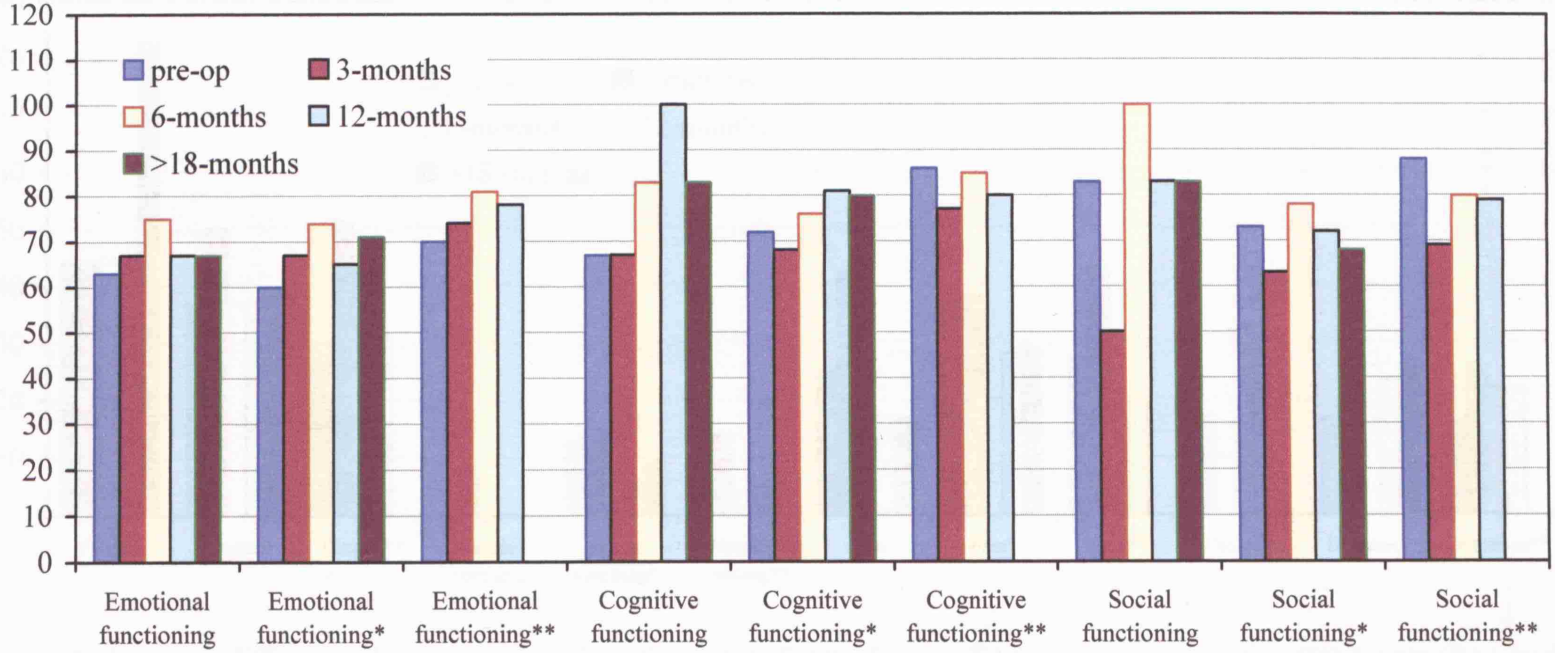
	Pre-op time (19 patients)		3-months time (10 patients)		6-months time (17 patients)		12-months time (13 patients)		>18-months time (33 patients)	
	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median
Global health status	56 (27)	54	48 (21)	50.0	59 (22)	66.7	61 (26)	66.7	64 (25)	66.7
Physical functioning	78 (26)	86.7	77 (15)	80.0	77 (25)	80.0	75 (26)	86.7	72 (26)	73.3
Role functioning	70 (30)	75.0	63 (26)	66.7	78 (32)	100	76 (26)	66.7	66 (30)	66.7
Emotional functioning	60 (25)	62.5	67 (28)	66.7	74 (23)	75.0	65 (26)	66.7	71 (23)	66.7
Cognitive functional	72 (29)	66.7	68 (28)	66.7	76 (26)	83.3	81 (30)	100	80 (22)	83.3
Social functioning	73 (32)	83.3	63 (23)	50.0	78 (35)	100	72 (30)	83.3	68 (33)	83.3
Fatigue	37 (21)	44.4	50 (16)	44.4	37 (28)	33.3	34 (27)	33.3	39 (29)	33.3
Nausea and vomiting	13 (26)	.00	13 (15)	8.3	14 (30)	.00	5 (8)	.00	10 (17)	.00
Pain	37 (35)	25.0	38 (26)	41.7	20 (18)	16.7	28 (32)	16.7	29 (33)	16.7
Dyspnoea	17 (17)	16.7	13 (23)	.00	26 (32)	33.3	23 (37)	.00	26 (32)	.00
Insomnia	44 (34)	33.3	53 (39)	50.0	45 (39)	33.3	39 (47)	.00	48 (39)	33.3
Appetite loss	43 (39)	33.3	40 (34)	33.3	26 (36)	.00	21 (26)	.00	26 (30)	33.3
Constipation	29 (33)	33.3	10 (32)	.00	16 (27)	.00	15 (38)	.00	22 (31)	.00
Diarrhea	7 (18)	.00	17 (28)	.00	4 (11)	.00	10 (16)	.00	8 (22)	.00
Financial difficulties	28 (40)	.00	23 (35)	.00	17 (32)	.00	18 (32)	.00	17 (31)	.00

Figure 2.4.1.17 (A): EORTC-C30 median scores at different stages
*mean-**mean scores from E. Hammerlid study (1997)



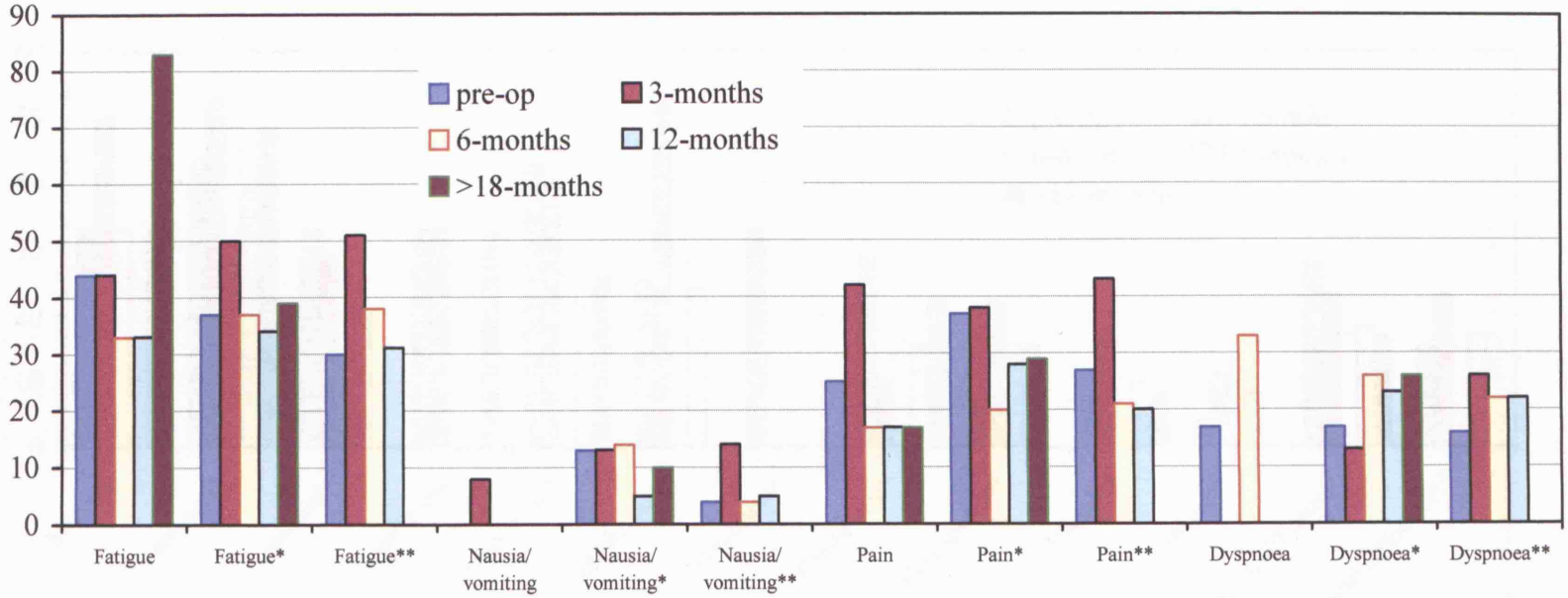
The graph illustrates the differences between patients' median scores for global health status (QL2), physical functioning (PF2) and role functioning (RF2) at different times of management. The QL2 median scores improved with time; the PF2 and RF2 median scores were similar to preoperative level at 12-months time; however, the RF2 median score at 6-month time was significantly high. There are no norms data for the EORTC-C30 to compare with, and the Hammerlid study (1997) did not report patients' data for >18-months.

Figure 2.4.1.17 (B): EORTC-C30 median scores at different stages
*mean-**mean scores from E. Hammerlid study (1997)



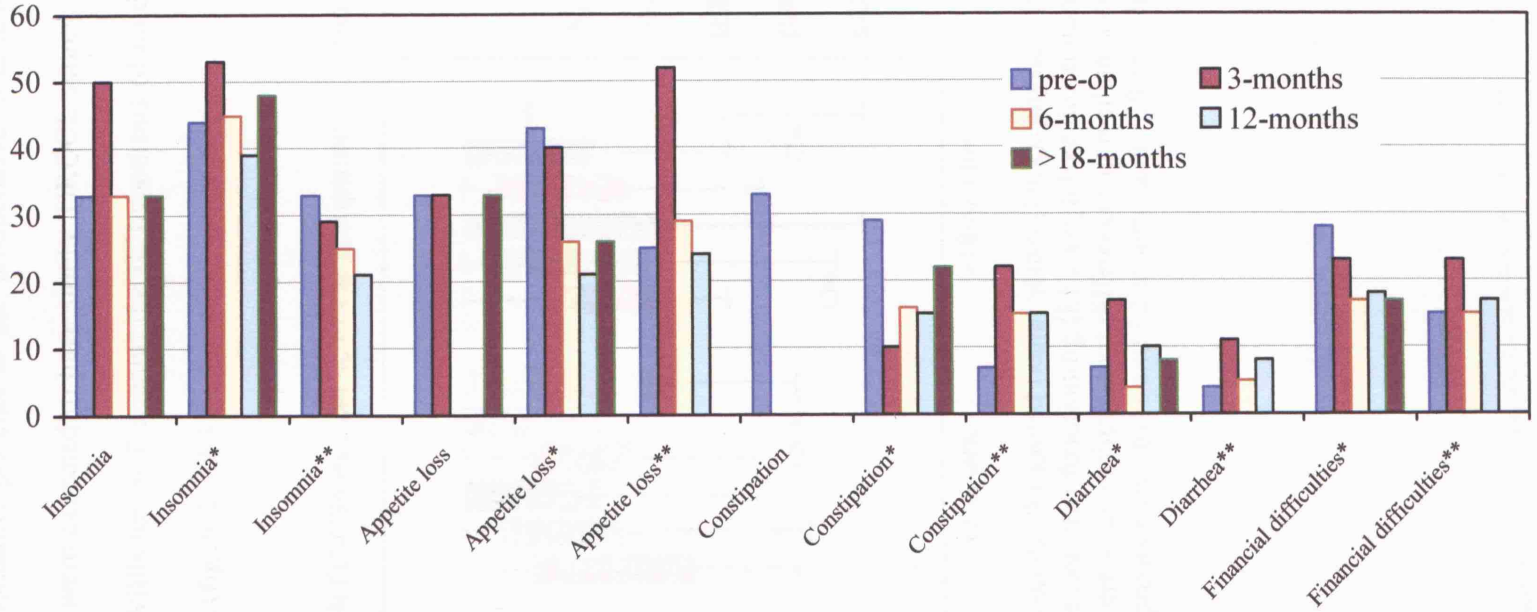
The graph shows the differences between patients' median scores for the emotional functioning (EF), cognitive functioning (CF), and social functioning (SF). The EF and SF median scores improved significantly at 6-months time then decreased to preoperative level. The CF at 12-month time was significantly higher than preoperative scores. There are no norms data for the EORTC-C30 to compare with, and the Hammerlid study (1997) did not report patients' data for >18-months.

Figure 2.4.1.17 (C): Patients' EORTC-C30 median scores at different stages
*mean-**mean scores from E. Hammerlid study (1997)



The graph shows the differences between patients' median scores for the fatigue (FA), nausea and vomiting (NV), pain (PA), and dyspnoea (DY). Fatigue scores were significantly high in patients at the 24-month time; and pain scores at 6-months time and after were lower than the preoperative score. Nausea/vomiting and dyspnoea did not constitute a significant problem postoperatively. There are no norms data for the EORTC-C30 to compare with, and the Hammerlid study (1997) did not report patients' data for >18-months.

Figure 2.4.1.17 (D): EORTC-C30 median scores at different stages
*mean-**mean scores from E. Hammerlid study (1997)

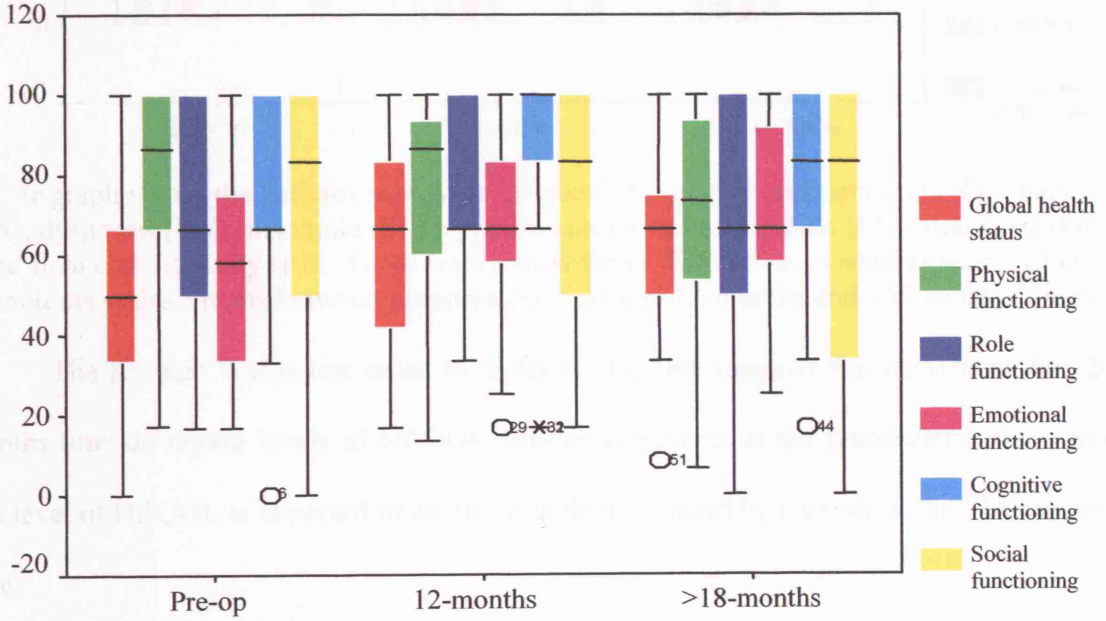


The graph shows the differences between patients' median scores for the symptoms of insomnia (SL), appetite loss (AP), constipation (CO), diarrhoea (DI), and financial difficulties (FI). Diarrhoea, financial difficulty and constipation were not significant problems to majority of the patients. Insomnia and appetite median scores were significantly better at 12-month time. The median score for diarrhoea and financial difficulties was 0 at all times; therefore it was omitted from the graph. There are no norms data for the EORTC-C30 to compare with, and the Hammerlid study (1997) did not report patients' data for >18-months.

2.4.1.4.1 Comparative analysis

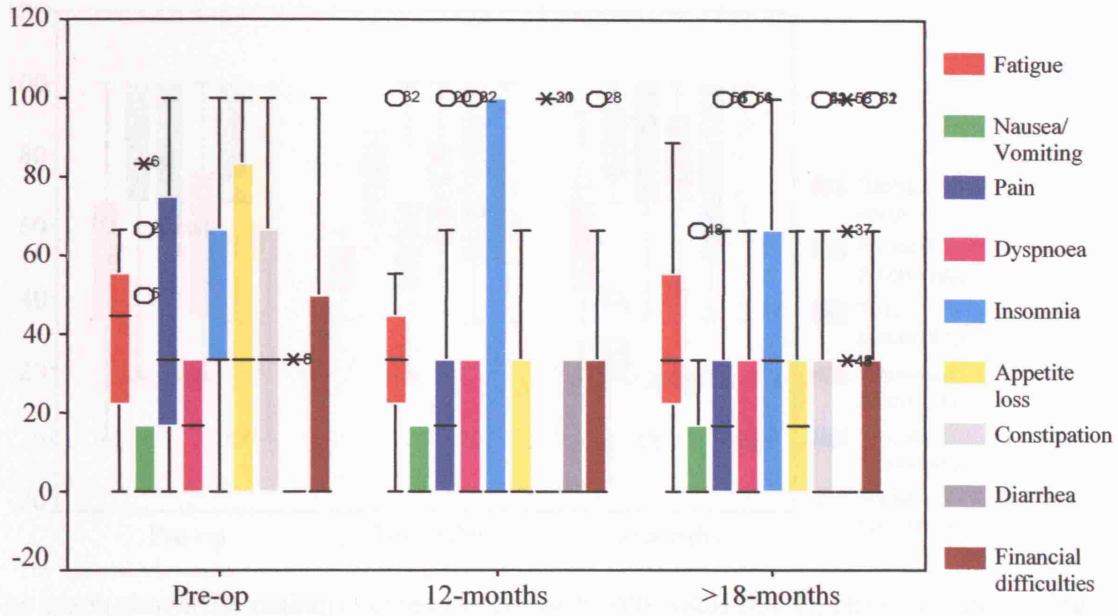
As in the SF-36 questionnaire, patients at the preoperative time and at the 12-months and >18-months times were expected to have similar HRQOL scores; therefore, it was thought that the Kruskal Willis test will support the H_0 hypothesis of no difference in median scores at all three times (figure 2.4.1.18).

Figure 2.4.1.18-A: EORTC-C30 median scores at preoperative, 12 and >18-months



The graph shows the patients scores for global health status (QL2), physical functioning (PF2), role functioning (RF), emotional functioning (EF), cognitive functioning (CF) and social functioning (SF). There were insignificant differences in median scores of all functional scales between preoperative time and 12-months and >18-months times.

Figure 2.4.1.18-B: EORTC-C30 median scores at preoperative, 12 and >18-months

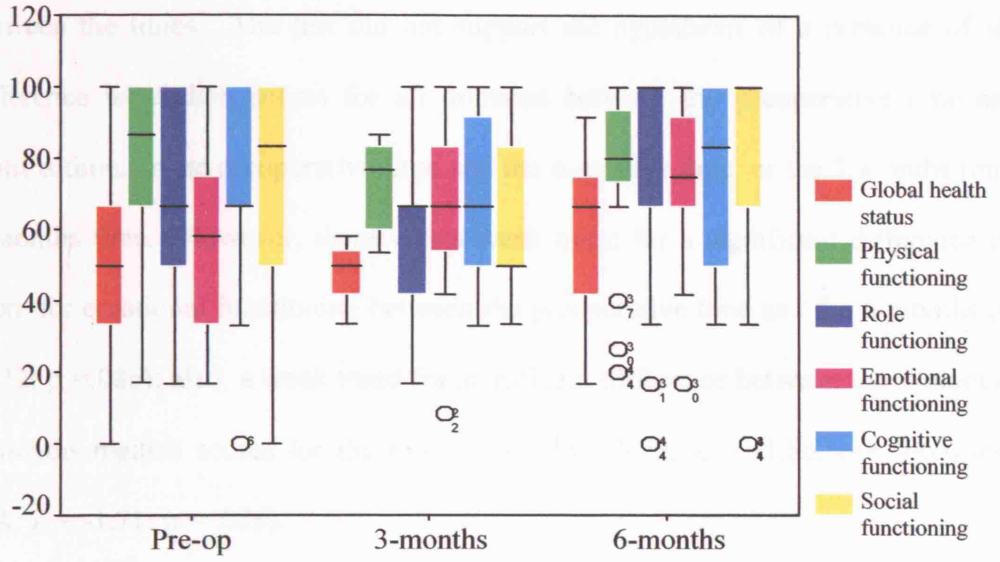


The graph shows the patients scores for fatigue (FA), nausea and vomiting (NV), pain (PA), dyspnoea (DY), insomnia (SL), appetite loss (AP), constipation (CO), diarrhoea (DI) and financial difficulty (FI). There were insignificant differences in median scores of all symptoms scales / items between preoperative time and 12-months and >18-months times.

The Kruskal Wallis test failed to reject the H_0, this suggests that patients at the 12-months time do regain levels of HRQOL similar to patients at the preoperative time, and this level of HRQOL is expected to continue as demonstrated by patients at the >18-months time.

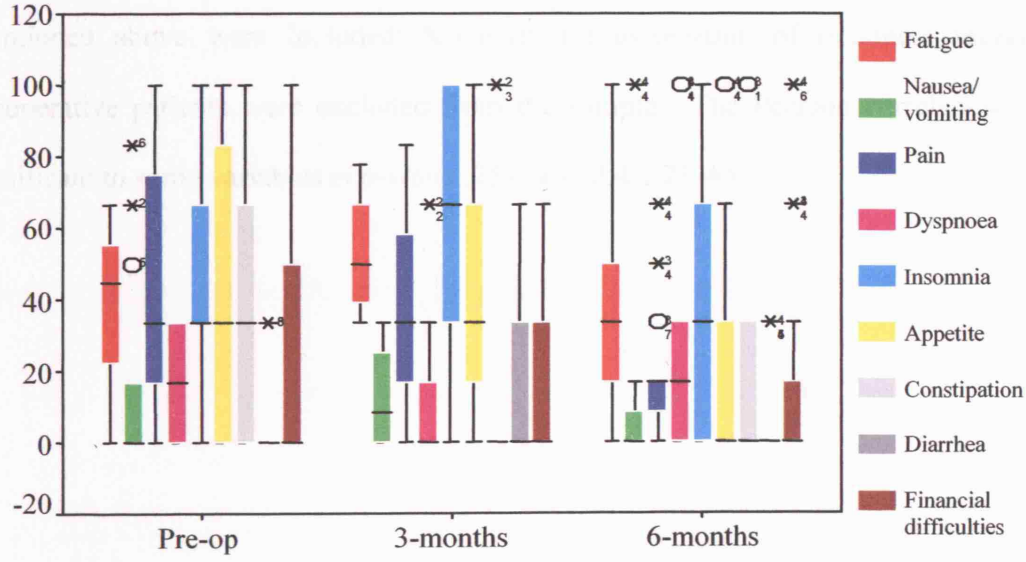
Oral and Pharyngeal cancer patients do go through a difficult time after the operation, and this is expected to be at its most at 3-months time; however, most patients do start to adapt to their life at the 6-months time. The differences in the patients' scores between the different times are demonstrated in figure 2.4.1.19.

Figure 2.4.1.19-A: EORTC-C30 median scores at preoperative, 3 and 6 months



The graph shows the patients scores for global health status (QL2), physical functioning (PF2), role functioning (RF), emotional functioning (EF), cognitive functioning (CF) and social functioning (SF). There were insignificant differences in median scores of functional scales between preoperative time and 3-months and 6-months times.

Figure 2.4.1.19-B: EORTC-C30 median scores at preoperative, 3 and 6 months



The graph shows the patients scores for fatigue (FA), nausea and vomiting (NV), pain (PA), dyspnoea (DY), insomnia (SL), appetite loss (AP), constipation (CO), diarrhoea (DI) and financial difficulty (FI). There were insignificant differences in median scores of symptoms scales / items between preoperative time and 3-months and 6-months times.

The Mann-Whitney-U test was used to test for significant differences in scores between the times. The test did not support the hypothesis of a presence of significant difference in median scores for all domains between the preoperative time and the 3-months time, or the preoperative time and the 6-months time, or the 3-months time and the 6-months time. However, there was a weak trend for a significant difference in median score for emotional functioning between the preoperative time and the 6-months time (Z = -1.72; p =.086); also, a weak trend for significant difference between the 3-months and the 6-months median scores for the role functioning (RF2: Z = -1.86; p = .063) and fatigue (FA: Z = -1.71; p = .088).

2.4.1.4.2 Correlation analysis

The sample was patients from the preoperative time and the 12 and >18-months times. For association of patients' demographics with HRQOL domains all the patients mentioned above were included; however, for association of treatment received the preoperative patients were excluded from the sample. The Pearson correlation test was significant to some variables at p-value .05 (table 2.4.1.23-A).

Table 2.4.1.23-A: Correlation of patients' characteristics and EORTC-C30 domains

		Global health status	Physical functioning	Role functioning	Social functioning	Fatigue	Nausea/ vomiting	Dyspnoea	Financial difficulties
Age	r		- .314				- .268		
	N		64				64		
	p-value		.011				.032		
Gender	r							.288	
	N							62	
	p-value							.023	
S. Tissue resection	r			- .309					
	N			46					
	P-value			.037					
Neck dissection	r	- .333		- .384	- .301	.377			.419
	N	46		46	46	46			45
	P-value	.024		.008	.042	.01			.004

Preoperative variables are patient's age, gender, and tumour size and neck state. Significant association of these variables to EORTC-C30 domains has been assessed by multiple regression analysis. None of the EORTC-C30 domain scores was significantly predicted by the listed preoperative variables. Treatment predictors are soft tissue resection anterior/lateral or posterior/medial to teeth, discontinuity bone resection, radiotherapy and level of neck dissection. Bone resection and level of neck dissection notably predicted worse scores in social functioning and financial difficulty (table 2.4.1.23-B: appendix VIII).

- Predicted social functioning score = 111.73 + (13.04 x Soft tissue resection$^{\infty}$) – (20.45 x Bone resection$^{\circ}$) – (19.13 x level of neck dissection†) – (7.21 x Radiotherapy††)
- Predicted financial difficulty score = -67.32 + (23.69 x Bone resection$^{\circ}$) + (8.37 x Soft tissue resection$^{\infty}$) + (25.64 x level of neck dissection†) + (5.35 x Radiotherapy††)

$^{\circ}$ Rim or marginal bone resection = 1 & Discontinuity bone resection = 2; $^{\infty}$ Anterior/ lateral to teeth soft tissue resection = 1 & Posterior/ medial to teeth soft tissue resection = 2; † I-III neck dissection = 1 & IV-V neck dissection = 2; †† No radiotherapy treatment = 1 & Radiotherapy treatment = 2

This means that patients going to have segmental bone removal and/or level IV-V neck dissection are likely to have financial and social functioning difficulties more than others. Therefore the interventional psychosocial support programs for such patients need to concentrate on these two important issues.

2.4.1.5 The EORTC H&N35 questionnaire

The EORTC H&N35 is a site specific HRQOL questionnaire and was made to complement the EORTC-C30 core questionnaire. The study aimed to examine the hypothesis that there is no significant difference in the scores of patients' HRQOL domains measured in the EORTC H&N35 at the preoperative time, 6-months time, 12-months time and at the >18-months time.

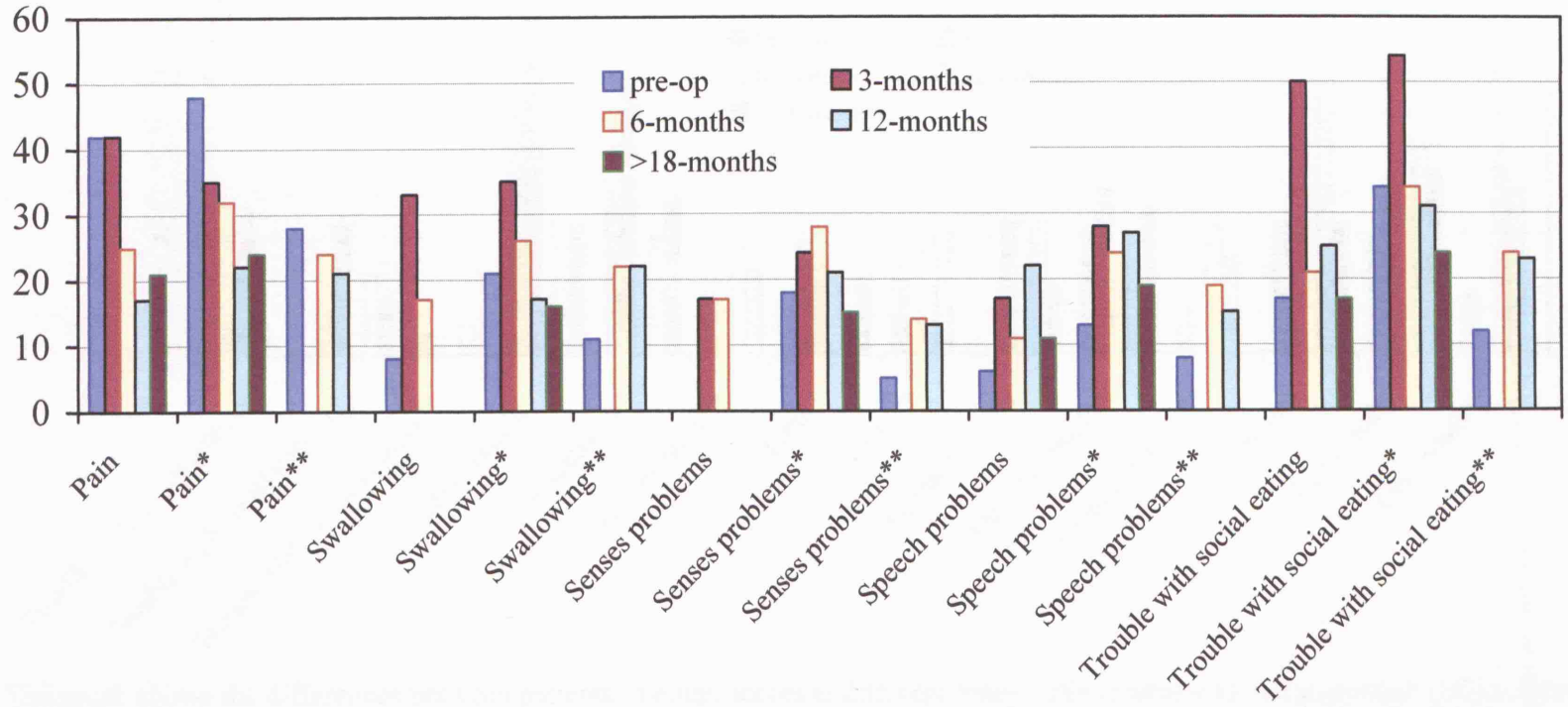
As described previously, the cross sectional studies examined patients' HRQOL at 5 different times of management. Each time had a different number of patients; 19 patients at the preoperative time, 10 patients in the 3-months time, 17 patients in the 6-months time, 13 patients at the 12-months time, and 33 patients in the >18-months time.

The number of patients at each time and their scores are summarized in table 2.4.1.24, and demonstrated in figures 2.4.1.20 (A, B, C) with results from a similar previous study (de Graeff et al. 1999). High scores indicate a high level of symptomatology/problems.

Table 2.4.1.24: Summary of the EORTC H&N35 scores at different times

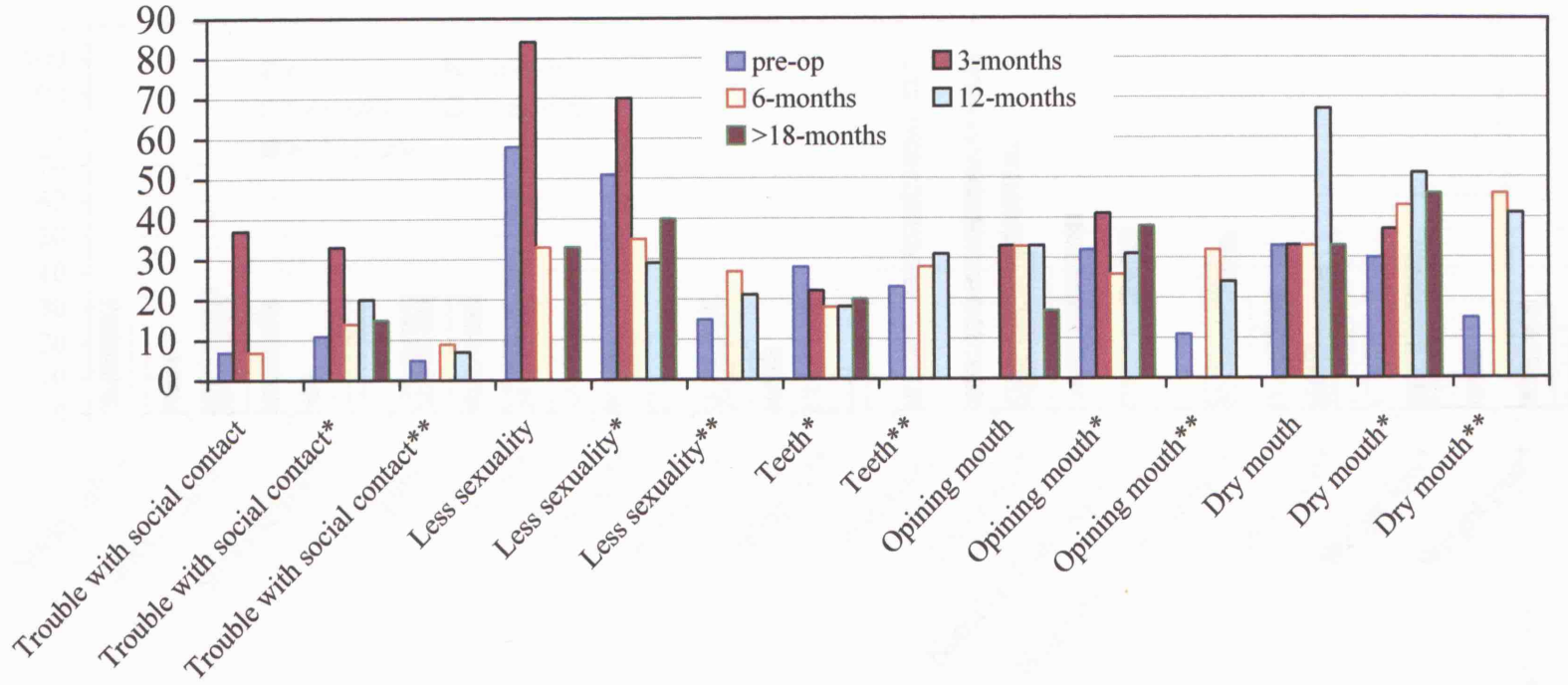
	Pre-op (19 patients)		3-months (10 patients)		6-months (17 patients)		12-months (13 patients)		>18-months (33 patients)	
	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median
Pain	48 (31)	41.7	35 (37)	41.7	32 (29)	25.0	22 (21)	16.7	24 (23)	20.8
Swallowing	21 (28)	8.3	35 (39)	33.3	26 (33)	16.7	17 (30)	.00	16 (24)	.00
Senses problems	18 (29)	.00	24 (32)	16.7	28 (39)	16.7	12 (21)	.00	15 (25)	.00
Speech problems	13 (19)	5.6	28 (27)	16.7	24 (30)	11.1	27 (30)	22.2	19 (20)	11.1
Trouble with Social eating	34 (35)	16.7	54 (39)	50	34 (41)	20.8	31 (33)	25	24 (28)	16.7
Trouble with Social contact	11 (14)	6.67	33 (26)	36.7	14 (25)	6.7	20 (30)	.00	15 (24)	.00
Less sexuality	51 (45)	58	70 (40)	83.5	35 (37)	33.3	29 (38)	.00	40 (39)	33.3
Teeth	28 (40)	.00	22 (44)	.00	18 (29)	.00	18 (32)	.00	20 (29)	.00
Opening mouth	32 (39)	.00	41 (40)	33.3	26 (32)	33.3	31 (37)	33.3	38 (43)	16.7
Dry mouth	30 (28)	33	37 (42)	33.3	43 (37)	33.3	51 (32)	66.7	46 (39)	33.3
Sticky saliva	35 (38)	33	33 (50)	.00	33 (39)	33.3	28 (41)	.00	32 (38)	16.7
Coughing	20 (21)	33	33 (24)	33.3	31 (32)	33.3	21 (22)	33.3	25 (25)	33.3
Feeling ill	33 (41)	.00	19 (24)	.00	18 (36)	.00	15 (29)	.00	18 (32)	.00
Pain killer	77 (44)	100	44 (53)	.00	41 (51)	.00	31 (48)	.00	55 (51)	100
Nutritional supplements	41 (51)	.00	50 (53)	50	31 (48)	.00	23 (44)	.00	33 (48)	.00
Feeding tube	18 (39)	.00	40 (52)	.00	35 (49)	.00	23 (44)	.00	3 (17)	.00
Weight loss	47 (52)	.00	20 (42)	.00	6 (24)	.00	.00	.00	16 (37)	.00
Weight gain	.00	.00	30 (48)	.00	29 (47)	.00	23 (44)	.00	22 (42)	.00

Figure 2.4.1.20(A): EORTC H&N35 median scores at different stages
*mean - **mean scores from A. de Graeff study (1999)



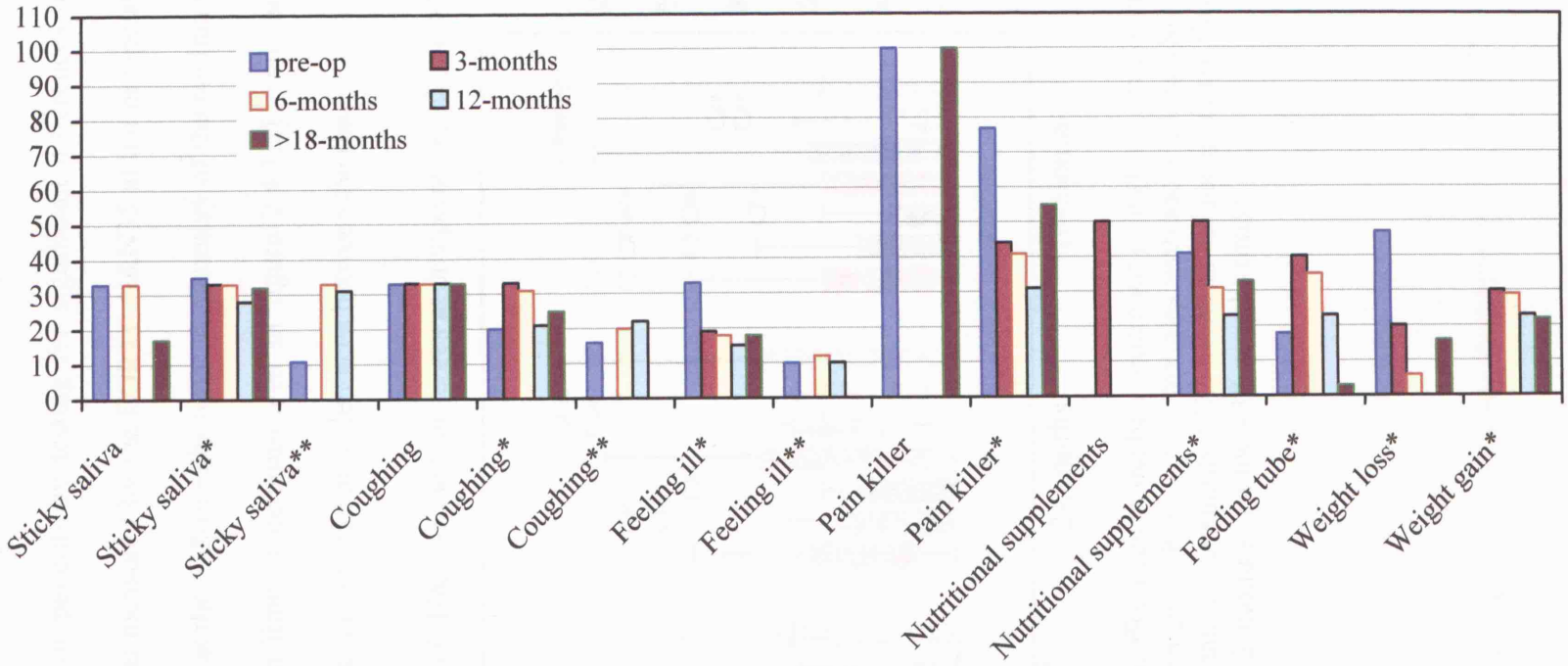
The graph shows the differences between patients' median scores at different times. Pain (PA) scores significantly decreases with time. Swallowing (SW) and senses problems (SE) scores at 12-months time are similar to scores at the preoperative time. Speech problems (SP) scores at the 12 months time are significantly higher than scores at the preparative time. Trouble with social eating (SO) scores at 12-months time are similar to scores at the preoperative level.

Figure 2.4.1.20(B): EORTC H&N35 median scores at different stages
*mean-**mean scores from A. de Graeff study (1999)



The graph shows the differences between patients' median scores at different times. The trouble with social contact (SC) scores at 12-months time are similar to preoperative scores level. Less sexuality (SX) scores at 12-months time significantly lower than preoperative scores. Teeth (TE) scores are similar at all times. Opening mouth (OM) and dry mouth (DR) scores at 12-months times are higher than preoperative scores.

Figure 2.4.1.20(C):EORTC H&N35 median scores at different stages
*mean-**mean scores from A. de Graeff study (1999)

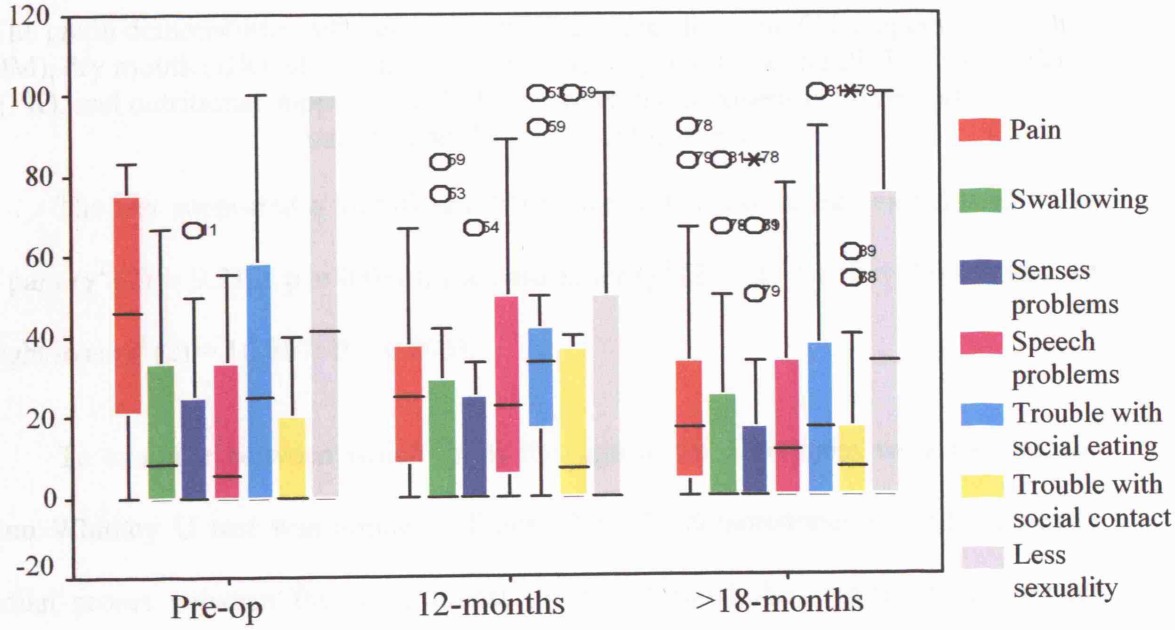


The graph shows the differences between patients' median scores at different times. Sticky saliva (SS) scores are lower than preoperative scores. Coughing (CO) and felt ill (FI) scores are similar at all times. Pain killers (PK) scores at the 12-months time are significantly lower than preoperative scores but increased to preoperative level at the >18-months time. Nutritional supplements (NU) score was high only in the 3-months time. Feeding tube (FE) and weight loss (WL) scores gradually decreases with time. Weight gain (WG) scores in all postoperative times were higher than preoperative scores.

2.4.1.5.1 Comparative analysis

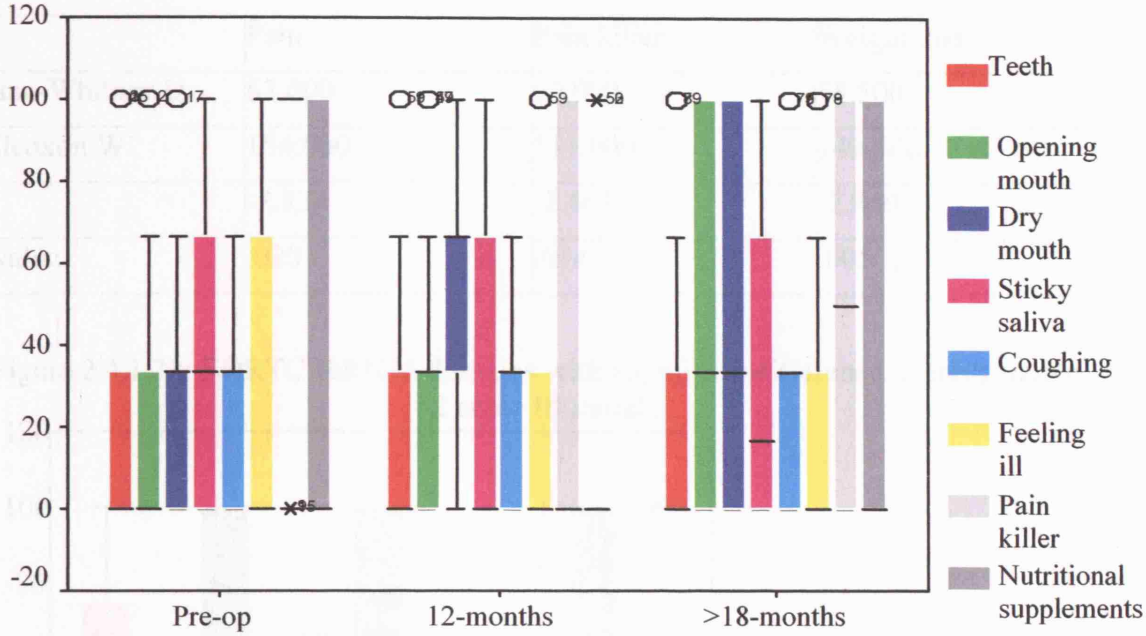
Previous studies have shown that oral and pharyngeal cancer patients do rehabilitate to a preoperative HRQOL level after one year. This assumption will be looked at in this sample of patients by testing for significant differences in median scores of HRQOL domains measured by the EORTC H&N35 at the preoperative time, at the 12-months time and at the >18-months time. A summery of the median scores for different domains at each time is demonstrated in figure 2.4.1.21, and the Kruskal Wallis test was used to test for significant differences between the times.

Figure 2.4.1.21-A: EORTC H&N35 median scores at preoperative, 12 and >18 months



The graph demonstrates differences in median scores for pain (PA), swallowing (SW), senses problems (SE), speech problems (SP), troubles with social eating (SO), trouble with social contact (SC) and less sexuality (SX) between the preoperative time and the 12-months and the >18-months times.

Figure 2.4.1.21-B: EORTC H&N35 median scores at preoperative, 12 and >18 months



The graph demonstrates differences in median scores for teeth (TE), opening mouth (OM), dry mouth (DR), sticky saliva (SS), coughing (CO), feeling ill (FI), pain killers (PK), and nutritional supplements (NU) between the preoperative time and the 12-months and the >18-months times.

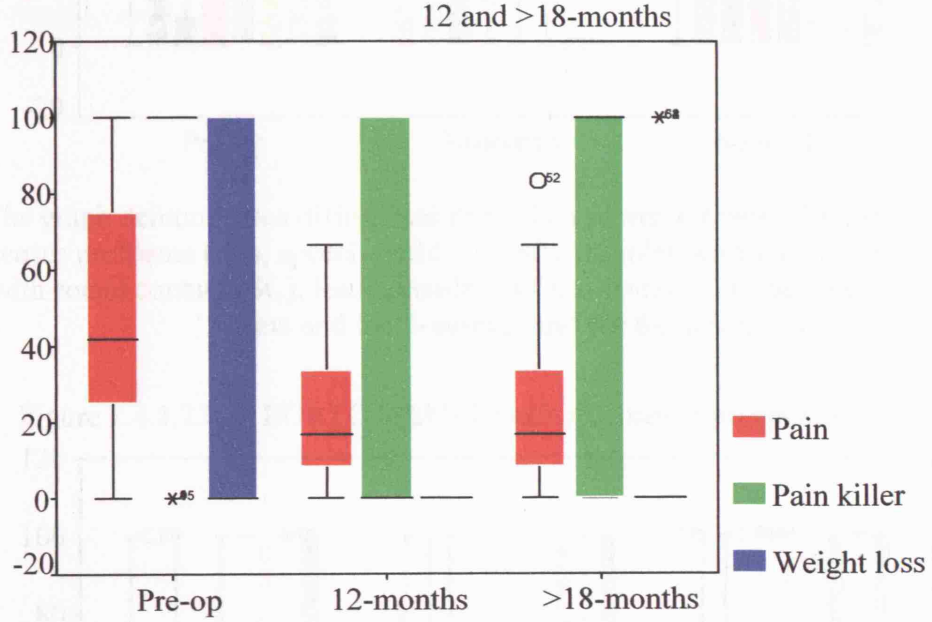
The test supported a significant difference in the median scores between times for pain (χ^2 (2) = 9.217; p = 0.010); for pain killer (χ^2 (2) = 6.161; P = 0.046); and for weight loss (χ^2 (2) = 10.807; P = 0.005).

To examine between which times the significant differences were located, the Mann Whitney U test was applied. Figure 2.4.1.22 demonstrates the differences in median scores between the three times; the test located the significant differences between the preoperative time and the 12-months time (table 2.4.1.25).

Table 2.4.1.25: EORTC H&N35 domains with significant difference between the preoperative and 12 and >18-months scores

	Pain	Pain killer	Weight loss
Mann-Whitney U	63.000	60.000	58.500
Wilcoxon W	154.000	151.000	149.500
Z	-2.333	-2.461	-2.840
P-value	.020	.014	.005

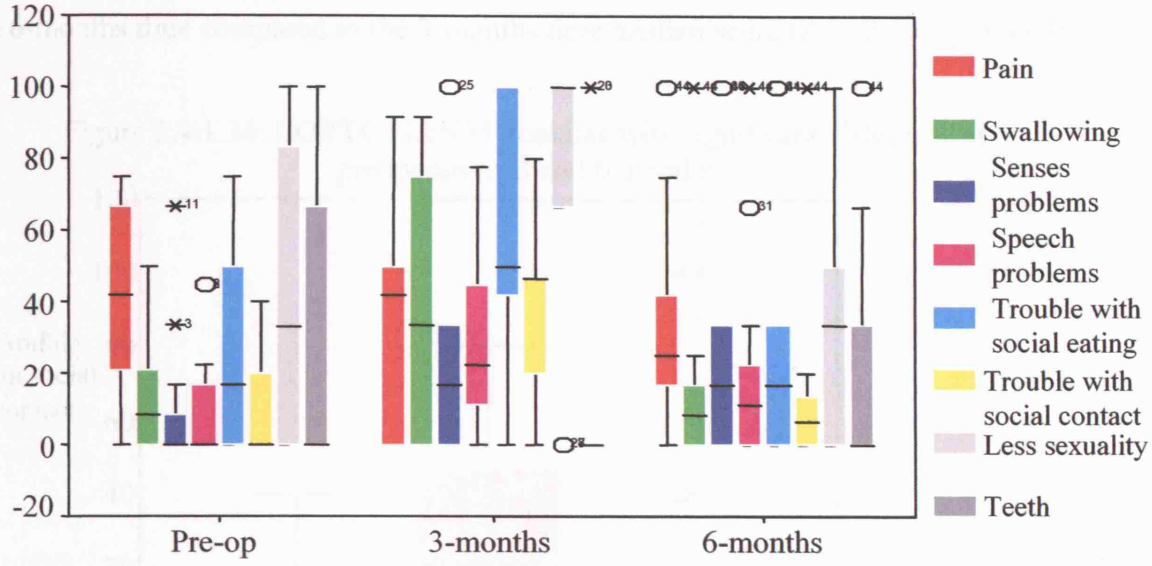
Figure 2.4.1.22: EORTC H&N35 domains with significant difference at preoperative, 12 and >18-months



The box plot graph shows the differences in pain (PA), pain killer (PK) and weight loss (WL) scores between different times of management.

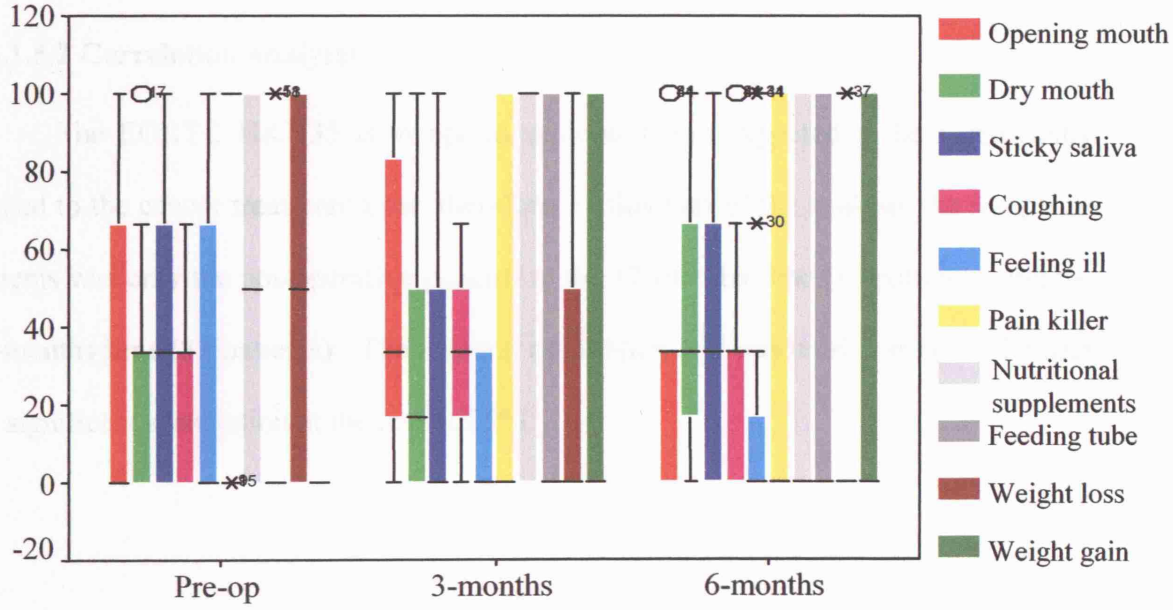
For a significant difference between the patients' preoperative median scores and the 3-months time median scores, also between median scores at the 3-months time and the 6-months time the Mann Whitney-U test was used. A summary of differences in the domains' median scores are demonstrated in figure 2.4.1.23.

Figure 2.4.1.23-A: EORTC H&N35 median scores at preoperative, 3 and 6 months



The graph demonstrates differences in median scores for pain (PA), swallowing (SW), senses problems (SE), speech problems (SP), troubles with social eating (SO), trouble with social contact (SC), less sexuality (SX), and teeth (TE) between the preoperative time and the 3-months and the 6-months times.

Figure 2.4.1.23-B: EORTC H&N35 median scores at preoperative, 3 and 6 months

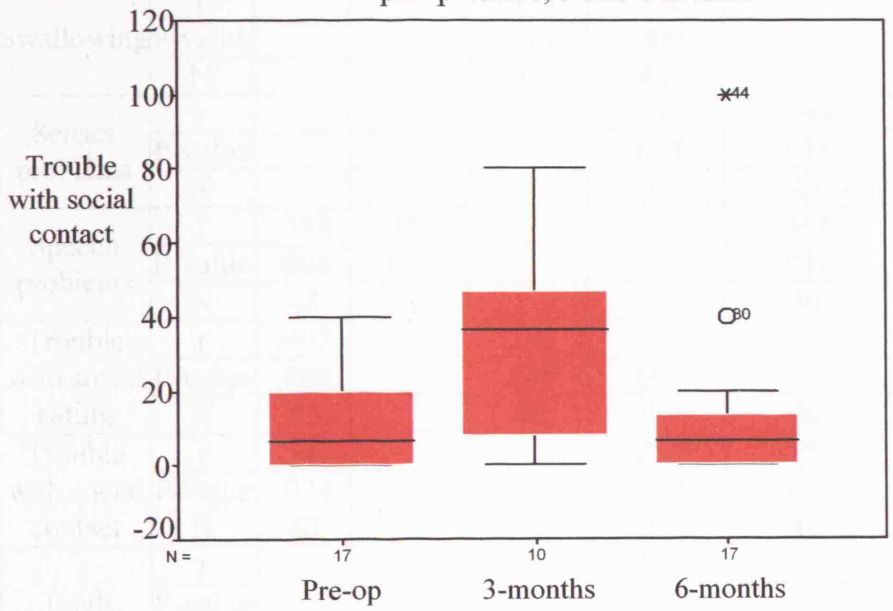


The graph demonstrates differences in median scores for opening mouth (OM), dry mouth (DR), sticky saliva (SS), coughing (CO), feeling ill (FI), pain killers (PK), nutritional supplements (NU), weight loss (WL), and weight gain (WG) between the preoperative time and the 3-months and the 6-months times.

As the difference was expected to be in one direction; the test was significant only for the trouble with social contact item (figure 2.4.1.24); where the median score significantly increased at the 3-months time compared to the preoperative time median

score (Z = -2.323; p = 0.023). However, the median score did improve significantly at the 6-months time compared to the 3-months time median score (Z = -2.193; p = 0.031).

Figure 2.4.1.24: EORTC H&N35 domains with significant difference at preoperative, 3 and 6 months



2.4.1.5.2 Correlation analysis

The EORTC H&N35 is symptom scale and was expected to be significantly related to the cancer treatment time, therefore, in this part of the analysis the sample of patients was only the postoperative patients at the 12-months time (13 patients), and the 24-months time (33 patients). The Pearson correlation test was used to explore the data for significant association at the level of 5%.

Table 2.4.1.26: Correlation of patients' demographics and EORTC H&N35 domains

		Tumor size	Bone resection	S tissue resection	Neck dissection	Re-construction	Radiothe.	Age	sex
Pain	r				.389				
	P-value				.008				
	N				45				
Swallowing	r			.375	.532		.299		
	P-value			.011	.000		.046		
	N			45	45		45		
Senses problems	r				.355	.364			.306
	P-value				.017	.014			.041
	N				45	45			45
Speech problems	r	.398	.365			.368	.347		
	P-value	.008	.013			.012	.018		
	N	43	46			46	46		
Trouble with social eating	r	.407		.293	.486	.342	.423		
	P-value	.007		.048	.001	.020	.003		
	N	43		46	46	46	46		
Trouble with social contact	r	.343			.295	.355		-.312	
	P-value	.024			.047	.016		.035	
	N	43			46	46		46	
Teeth	r				.332				
	P-value				.028				
	N				44				
Opening mouth	r	.402	.337						
	P-value	.008	.023						
	N	42	45						
Dry mouth	r				.435	.319			
	P-value				.003	.033			
	N				45	45			
Sticky saliva	r			.429	.405		.349		.408
	P-value			.003	.006		.019		.005
	N			45	45		45		45
Coughing	r			.303	.391			-.312	
	P-value			.043	.008			.037	
	N			45	45			45	
Pain killer	r						-.302		
	P-value						.041		
	N						46		
Nutritional supplement	r				.341				
	P-value				.020				
	N				46				
Feeding tube	r	.377							
	P-value	.013							
	N	43							

Many symptoms were significantly correlated with the patients' demographics (table 2.4.1.26); therefore, a regression analysis was performed. Preoperative variables were the patient's age, gender, and tumour size and neck state. Multiple regression

analysis shows the followings: large tumours significantly predicted worse scores for social eating and feeding tube; positive neck nodes significantly predicted worse scores for social eating and social contact and senses problems; and increased age significantly predicted worse scores for senses problems. Treatment variables were discontinuity bone resection, anterior/lateral or posterior/medial to teeth soft tissue resection, level of neck dissection and radiotherapy. Discontinuity bone resection significantly predicted worse scores for pain, swallowing, speech, social eating, social contact and opening mouth wide. Levels IV-V of neck dissection predicted worse scores for swallowing, social eating, social contact, dry mouth, and coughing. Posterior/medial to teeth soft tissue resection predicted worse scores for sticky saliva. Radiotherapy predicted worst scores for swallowing, social eating, teeth, and sticky saliva (appendix VIII - table 2.4.1.27-B).

The predictability equations are formulated below; however, when applying the equation one must refer to table 2.4.1.28 for the predictor value. It is important to notice that these predictions are for patients' domain scores at 12 and >18-months times.

- Predicted score for problems with social eating = -45.11 + (0.31 x patient age) + (10.53 x gender) + (19.02 x tumour size) + (19.25 x neck node status)

- Predicted score for problems with social contact = -1.77 – (0.17 x patient age) + (7.15 x gender) + (4.68 x tumour size) + (18.23 x neck node status)

- Predicted score for feeding tube = -58.774 + (0.122 x patient age) + (16.91 x gender) + (19.21 x tumour size) + (14.589 x neck node status)

- Predicted score for senses problems = -59.03 + (0.70 x patient age) + (9.82 x gender) + (3.55 x tumour size) + (24.65 x neck node status)

- Predicted pain score = -35.21 + (18.23 x type of bone resection) + (10.65 x type of soft tissue resection) + (9.89 x level of neck dissection) + (7.46 x radiotherapy)

- Predicted Swallowing score = -71.37 + (20.27 x type of bone resection) + (11.82 x type of soft tissue resection) + (17.93 x level of neck dissection) + (11.81 x radiotherapy)

- Predicted score for speech problems = -52.17 + (25.81x type of bone resection) + (7.84 x type of soft tissue resection) + (7.95 x level of neck dissection) + (9.99 x radiotherapy)

- Predicted score for problems with social eating = -84.96 + (31.41x type of bone resection) + (11.17 x type of soft tissue resection) + (17.37 x level of neck dissection) + (19.77 x radiotherapy)

- Predicted score for problems with social contact = -35.17 + (17.65 x type of bone resection) – (1.564 x type of soft tissue resection) + (13.65 x level of neck dissection) + (7.31 x radiotherapy)

- Predicted score for teeth = -37.03 + (18.62 x type of bone resection) – (8.50 x type of soft tissue resection) + (14.77 x level of neck dissection) + (18.52 x radiotherapy)

- Predicted score for opening mouth = -57.50 + (43.91 x type of bone resection) – (1.45 x type of soft tissue resection) + (15.44 x level of neck dissection) + (11.78 x radiotherapy)

- Predicted score for dry mouth = -7.13 + (2.12 x type of bone resection) – (4.53 x type of soft tissue resection) + (27.66 x level of neck dissection) + (9.36 x radiotherapy)

- Predicted score for sticky saliva = -85.87 + (21.79 x type of bone resection) + (21.17 x type of soft tissue resection) + (15.21 x level of neck dissection) + (21.56 x radiotherapy)

- Predicted score for coughing = -32.63 + (11.11 x type of bone resection) + (8.53 x type of soft tissue resection) + (15.53 x level of neck dissection) + (3.82 x radiotherapy)

Table 2.4.1.28: Predictors' values for EORTC H&N35 domains scores

	Value = 1	Value = 2
Age	Patient's age in years	
Gender	Female	Male
Tumor size	T_1 & T_2	T_3 & T_4
Neck node status	negative	positive
Bone resection	No or Rim resection	Maxillectomy / Mandibulectomy
Soft tissue resection	Anterior or Lateral to teeth	Posterior or Medial to teeth
Level of neck dissection	I – III	IV – V
Radiotherapy	No	Yes

2.4.2 The longitudinal analysis (9 patients):

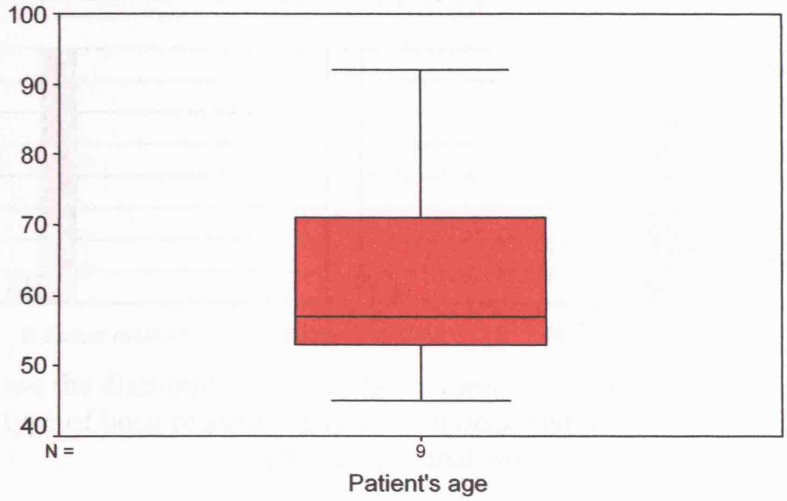
2.4.2.1 Patients' characteristics

Patients in this section completed the HRQOL questionnaires preoperatively and at 6-month postoperatively. The median age was 57 years with a range of 45 to 92 years and a mean of 63 years (SD 16). Five patients (56%) were less than 65 years old, and 4 patients (44%) more than 65 years. Although, there were more males (6) than females (3); male patients (median 53 years) tended to be younger than females (median 85 years). All patients included have squamous cell carcinoma (table 2.4.2.1) and (figure 2.4.2.1-A to 2.4.2.1-E).

Table 2.4.2.1: Patients' description in the longitudinal analysis (9 patients)

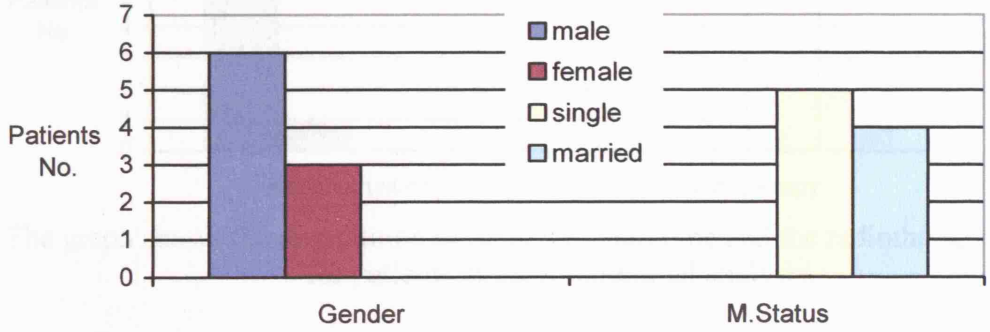
Patients age	Mean	63(SD:16)
	Median	57
Patients' gender	Male	6
	Female	3
Marital status	Married	4
	Single/widow	5
Tumour size	T1 & T2	3
	T3 & T4	6
Lymph node involvement	Negative	5
	Positive	4
Relation of soft tissue resection to teeth	Ant. or lat.	1
	Post. or med.	8
Bone resection	No or marginal	8
	Complete	1
Neck dissection	I-III	6
	IV-V	3
Reconstruction	Vascular flap	8
	Non vascular	1
Radiotherapy	Yes	6
	No	3

Figure 2.4.2.1 (A): Patients' age



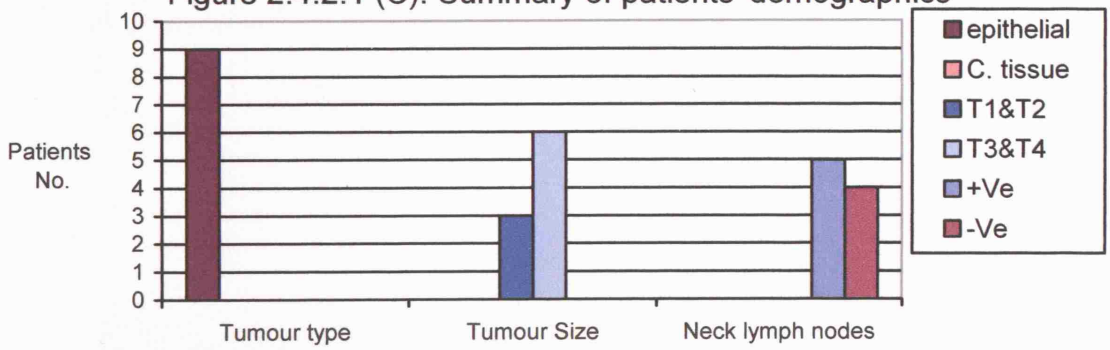
The box plot shows the age range of the patients included in the longitudinal analysis as well the median age.

Figure 2.4.2.1 (B): Summary of patients' demographics



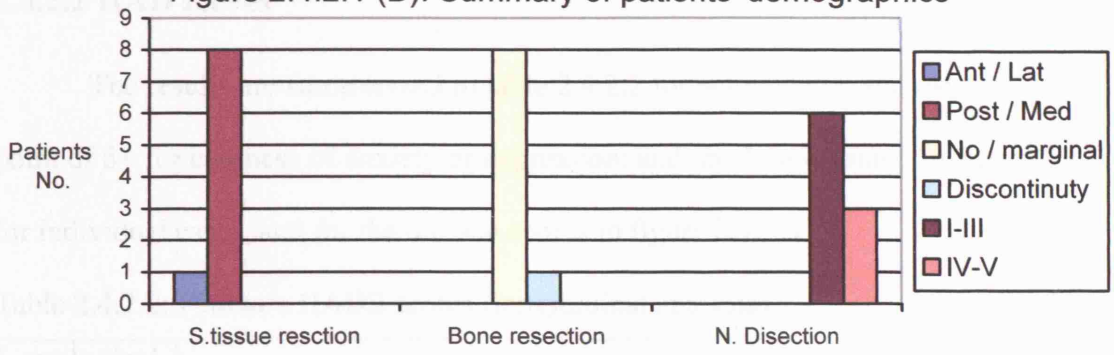
The graph shows the gender and marital status distribution of patients included in the longitudinal analysis

Figure 2.4.2.1 (C): Summary of patients' demographics



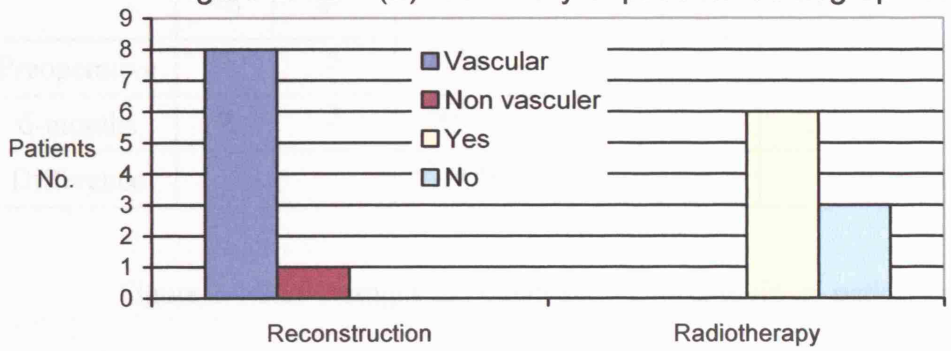
The graph shows the distributions of tumour type and size and state of the neck lymph nodes of patients in the longitudinal analysis.

Figure 2.4.2.1 (D): Summary of patients' demographics



The graph shows the distributions of treatment variables (relation of soft tissue resection to teeth, type of bone resection and level of neck dissection) for patients in the longitudinal analysis.

Figure 2.4.2.1 (E): Summary of patients' demographics



The graph shows the distribution of reconstruction type and the radiotherapy treatment for patients in the longitudinal analysis.

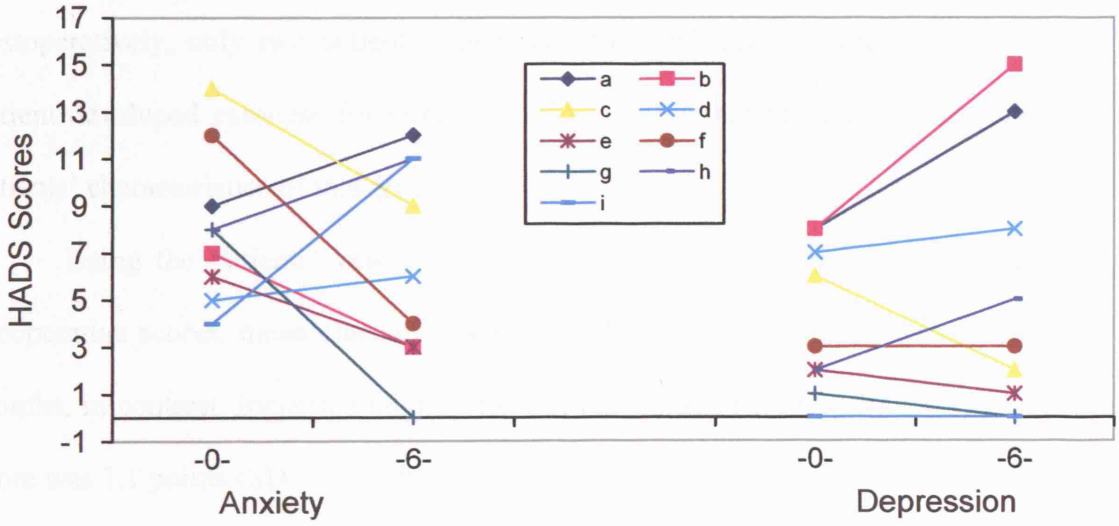
2.4.2.2 HAD scores

The results are summarized in table 2.4.2.2 for actual value and using the cut off point of 8+ for caseness of anxiety or depression; and are demonstrated in figure 2.4.2.2 for individual cases, and for the median scores in figure 2.4.2.3.

Table 2.4.2.2: Patient's HADS scores (longitudinal analysis)

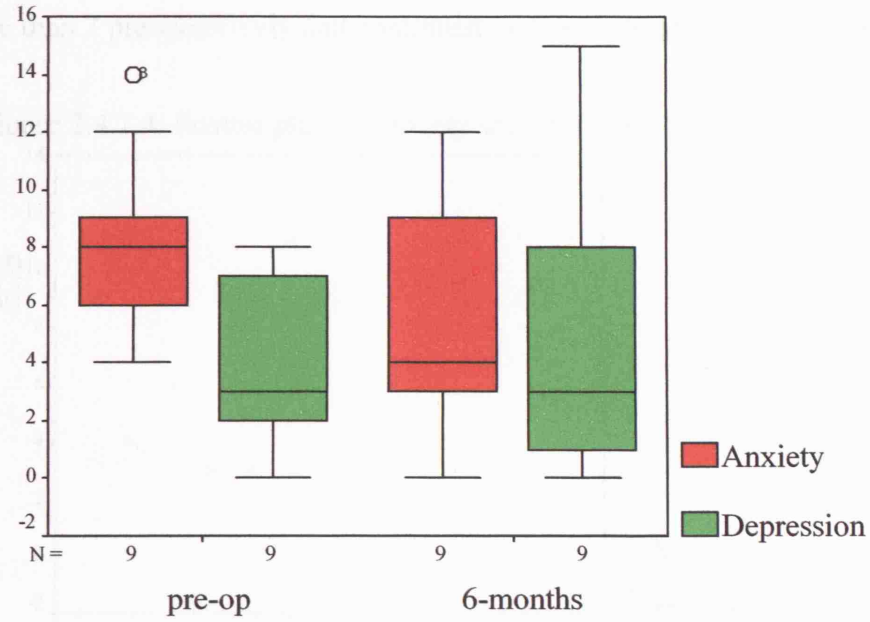
Longitudinal analysis	Anxiety				Depression			
	No of patients		Mean (SD)	Median	No of patients		Mean (SD)	Median
	<8	8+			<8	8+		
Preoperative	4	5	8(3)	8	7	2	4(3)	3
6-months	6	3	6(4)	4	6	3	5(5.6)	3
Difference			-2.3(4)				+1.1(3)	

Figure 2.4.2.2: Changes in HADS scores for individual patient over 6-months



The graph shows the changes of anxiety and depression scores for individual patients over 6-months period.

Figure 2.4.2.3: Changes in HADS scores over 6-months



The box plot graph shows the differences in median scores for anxiety and depression between the preoperative time and the 6-mnths time.

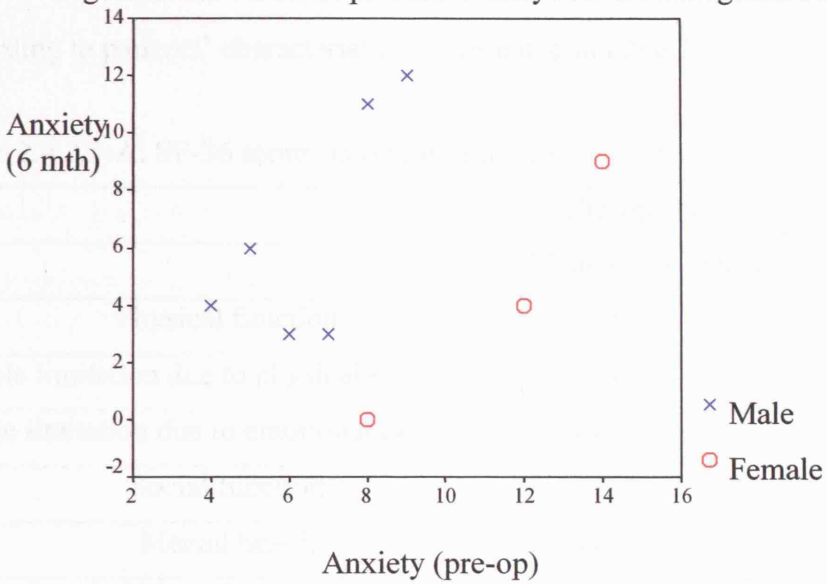
In the preoperative time, there were 5 out of 9 patients with a score more than 7 and thus qualified for caseness of anxiety. The median score was 8; 6-months postoperatively, only two patients maintained this high score (more than 7) and one patient developed caseness for anxiety. Table 2.4.2.3 (appendix IV) summarizes the patients' characteristics of this group.

Using the patients' raw scores, anxiety scores at 6-months were lower than preoperative scores, mean change in score was 2.3 points (SD: 4.3). Depression at 6-months, in contrast, increased slightly than in preoperative scores, the mean change in score was 1.1 points (SD: 3.4) (table 2.4.2.2).

To test for the predictability of patients' preoperative anxiety scores to postoperative anxiety scores at 6-months time, a scatter plot was created (figure 2.4.2.4). This association was not significant for raw scores when tested by the Pearson correlation test ($r = 0.32$; $n = 9$; $p = 0.4$); however, when using the cut-off point of 7 for caseness of anxiety, there was trend for association between anxiety preoperatively and

6-months postoperatively (χ^2 (1) = 3.6; p = .058). This is because 3 out of 5 patients scored more than 7 preoperatively and continued to score more than 7 postoperatively.

Figure 2.4.2.4: Scatter plot for anxiety scores in longitudinal analysis



The scatter plot graph shows that 3 patients with 8+ anxiety score after 6 months scored 8+ at the preoperative time.

The paired t-test was used to test for any significant change between the preoperative scores and 6-months after. Paired t-test used here was exceptional, but only because the differences between the two readings were normally distributed. However, there was no indication for significant difference in the individual's anxiety mean scores measured in the HADS before and 6-months after the surgery (t (8) = 1.63; p = .14). Even when tested by the Wilcoxon test. This finding supports the hypothesis that high preoperative anxiety scores predict high anxiety scores postoperatively.

Table 2.4.2.4: Test for significant changes in patients HAD scores

Wilcoxon Signed Ranks Test	Anxiety (0 - 6months)	Depression (0 - 6months)
Z	-1.550	-.851
Asymp. Sig. (2-tailed)	.121	.395

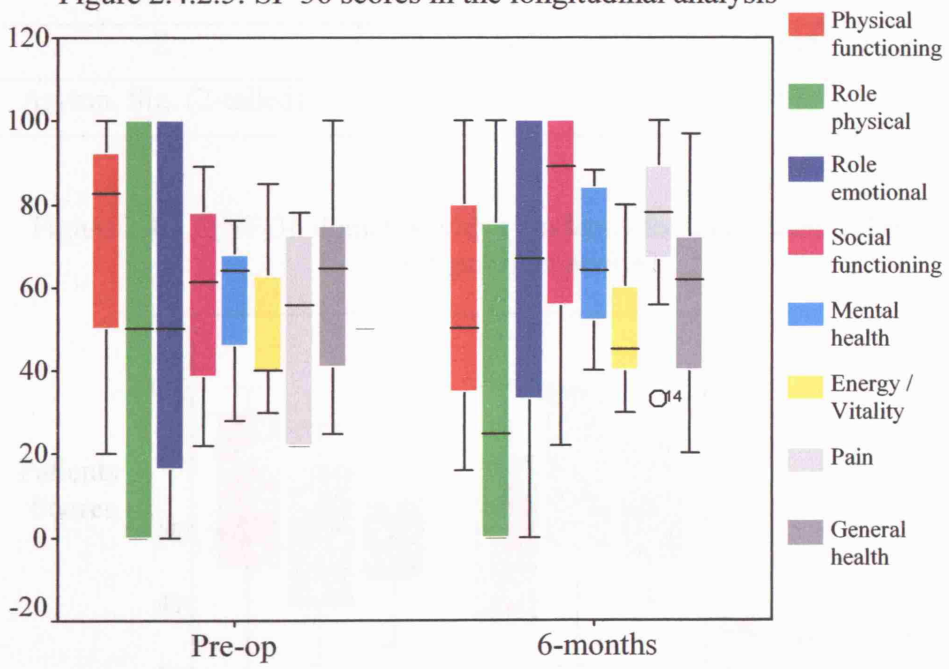
2.4.2.3 The SF-36 questionnaire

A summary of the domains scores at both times is presented in table 2.4.2.5-A, and demonstrated in figure 2.4.2.5; however, a detailed report of means and medians according to patients' characteristics is presented in table 2.4.2.5-B (appendix VII).

Table 2.4.2.5-A: SF-36 scores in longitudinal analysis (9 patients)

	Pre-operative		6-months	
	Mean (SD)	Median	Mean (SD)	Median
Physical function	71 (28)	83	55 (28)	50
Role limitation due to physical problems	50 (48)	50	37 (43)	25
Role limitation due to emotional problems	54 (43)	50	56 (41)	66.7
Social function	58 (24)	61	75 (33)	89
Mental health	58 (16)	64	66 (18)	64
Energy/Vitality	50 (18)	40	50 (16)	45
Pain	50 (25)	56	73 (20)	78
General health perception	61 (25)	65	56 (26)	62

Figure 2.4.2.5: SF-36 scores in the longitudinal analysis



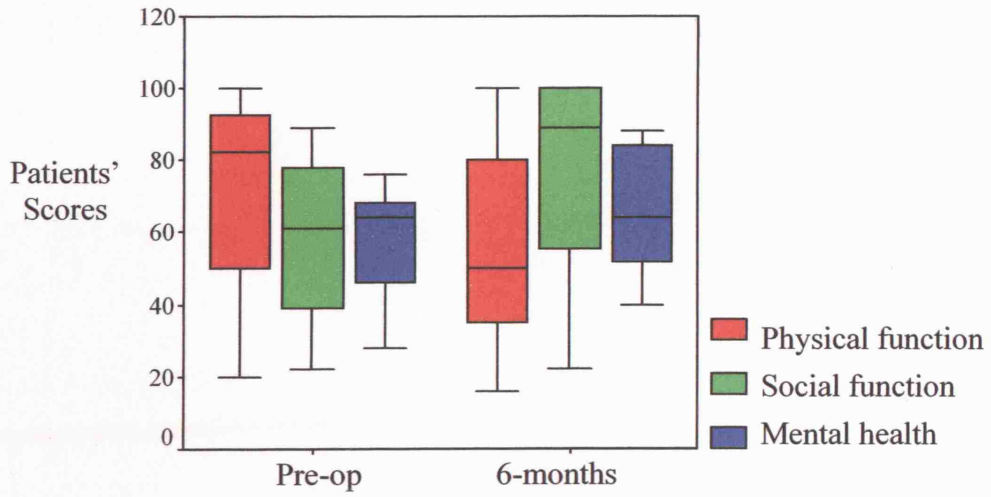
The box plot shows insignificant changes in patients' median scores at 6-months stage from preoperative stage for all the SF-36 domains, although there was a tendency for significant improvement for social functioning (SF) and mental health (MH)

There is no obvious flooring effect (concentration of low scores) at the preoperative time except for role limitation due to physical functioning; and this may question the ability of the questionnaire to measure change for individuals with low scores in this domain postoperatively. Most patients are expected to be in the rehabilitation time and adapting to their life by the fifth month after the operation; therefore, it is of value to check for the difference in domains scores between preoperative time and the 6-month postoperatively. The Wilcoxon-Signed rank test was used to test for significant differences between individual's scores at the two times for each domain. The test did not support the hypothesis of having significant differences in the median of domains scores between the times (table 2.4.2.6); however, there was a tendency for physical functioning, social functioning and mental health to have a significant difference at 6-month time from the preoperative level (figure 2.4.2.6).

Table 2.4.2.6: SF-36 domains with significant difference between preoperative and 6-months scores

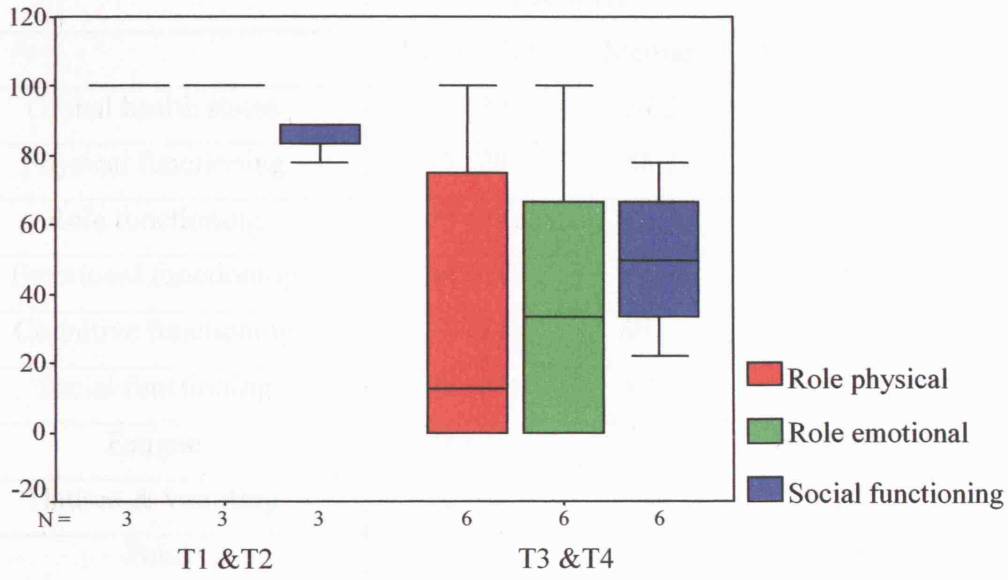
Wilcoxon Signed rank Test	Physical functioning	Social functioning	Mental health
Z	-1.682	-1.845	-1.876
Asymp. Sig. (2-tailed)	.092	.065	.061

Figure 2.4.2.6: SF-36 domains with a tendency for significant difference in the longitudinal analysis



Generally, there was no notable association between any of the patients' characteristics and the SF-36 domains; except for the tumour size at the preoperative time where T_3&T_4 patients tended to have lower scores in social functioning, role limitation due to emotional problem and role limitation due to physical problems (figure 2.4.2.7).

Figure 2.4.2.7: SF-36 domains with a tendency for significant association with tumour size at preoperative stage



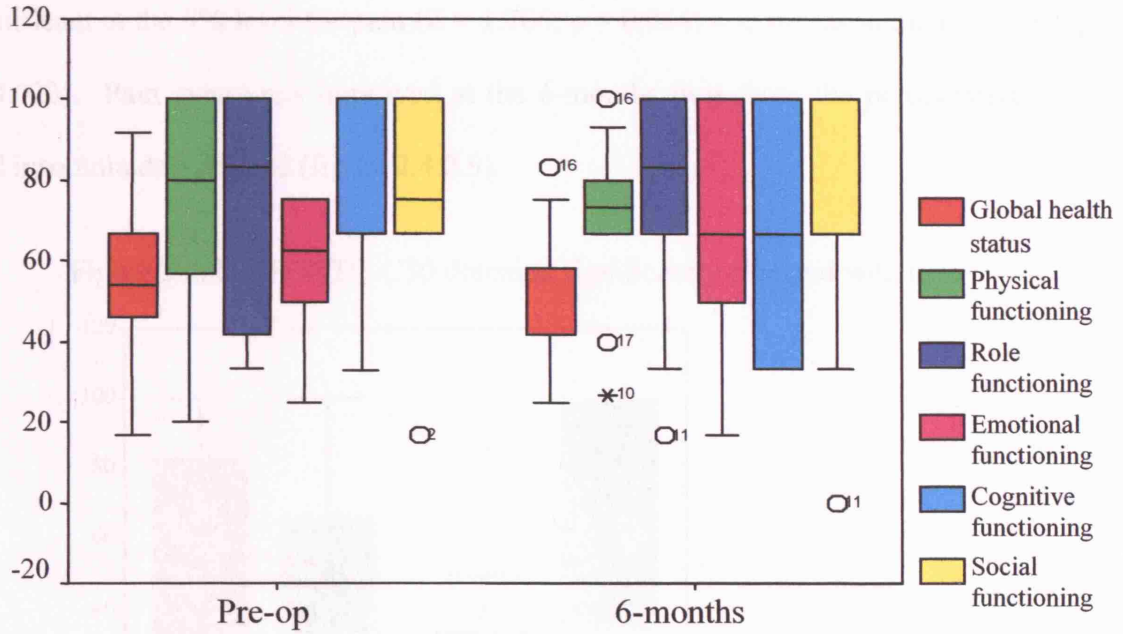
2.4.2.4 The EORTC-C30 questionnaire

Nine patients completed the EORTC-C30 questionnaire preoperatively and 6-months thereafter. A summary of the domains scores in both times is presented in table 2.4.2.7 and demonstrated in figure 2.4.2.8.

Table 2.4.2.7: EORTC-C30 scores in the longitudinal analysis (9 patients)

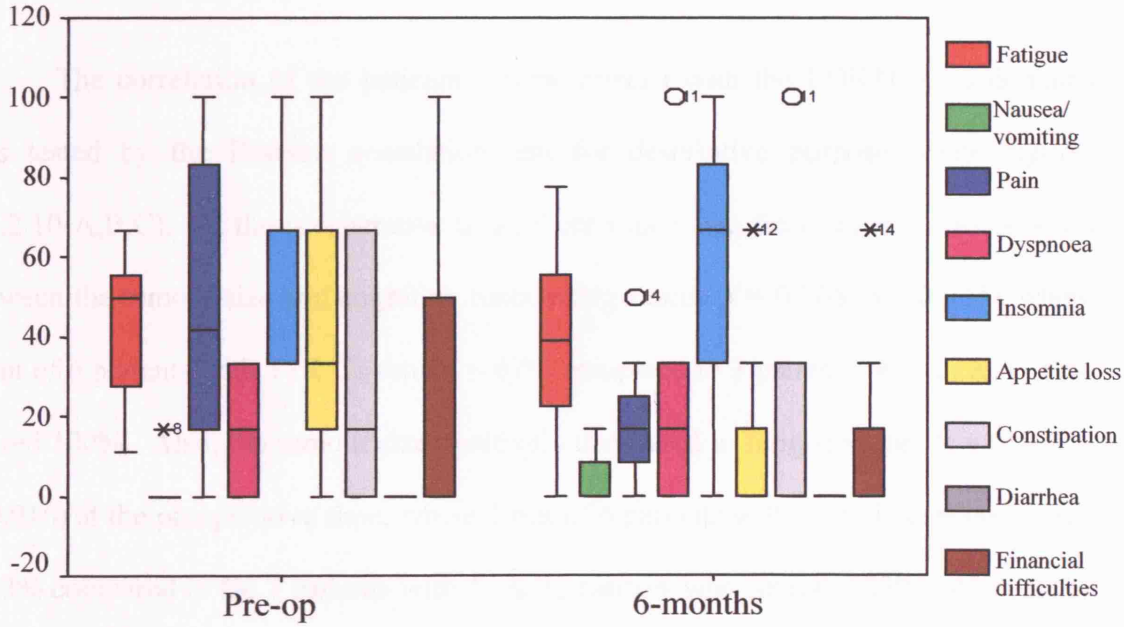
	Pre-operative		6-months	
	Mean (SD)	Median	Mean (SD)	Median
Global health status	55 (22)	54.2	50 (19)	41.7
Physical functioning	77 (28)	86.7	70 (24)	73.3
Role functioning	76 (29)	83.3	72 (30)	83.3
Emotional functioning	64 (21)	66.7	68 (29)	66.7
Cognitive functioning	78 (24)	66. 7	69 (32)	66.7
Social functioning	78 (28)	83.3	76 (36)	100
Fatigue	38 (23)	44.4	43 (26)	44.4
Nausea & vomiting	2 (6)	.00	13 (27)	.00
Pain	43 (38)	33.3	20 (16)	16.7
Dyspnoea	15 (18)	.00	26 (32)	33.3
Insomnia	44 (29)	33.3	63 (35)	66.7
Appetite loss	37 (35)	33.3	22 (37)	.00
Constipation	26 (32)	.00	22 (33)	.00
Diarrhea	.00	.00	.00	.00
Financial difficulties	25 (39)	.00	13 (25)	.00

Figure 2.4.2.8(A): EORTC-C30 median scores in longitudinal analysis



The box plot graph illustrates changes in patients' median scores for global health status (QL2), physical functioning (PF2), role functioning (RF), emotional functioning (EF), cognitive functioning (CF) and social functioning (SF) over a period of 6-months.

Figure 2.4.2.8(B): EORTC-C30 median scores in longitudinal Analysis

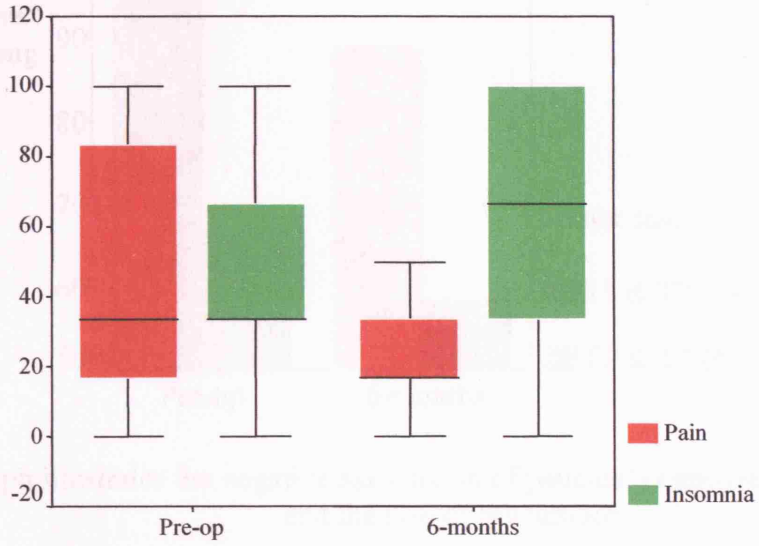


The box plot graph illustrates changes in patients' median scores for fatigue (FA), nausea and vomiting (NV), pain (PA), dyspnoea (DY), insomnia (SL), appetite loss (AP), constipation (CO), diarrhoea (DI) and financial difficulty (FI) over a period of 6-months.

To test for significant differences between the preoperative time and the 6-months time, the Wilcoxon Signed Ranks Test was used. It was expected that the

change would be directional, so the two tailed p-value will be halved. The test was significant at the 5% level for pain (Z = 1.706; p = 0.044) and for insomnia (Z = 1.89; p = 0.023). Pain symptoms improved at the 6-months time from the preoperative time and insomnia deteriorated (figure 2.4.2.9).

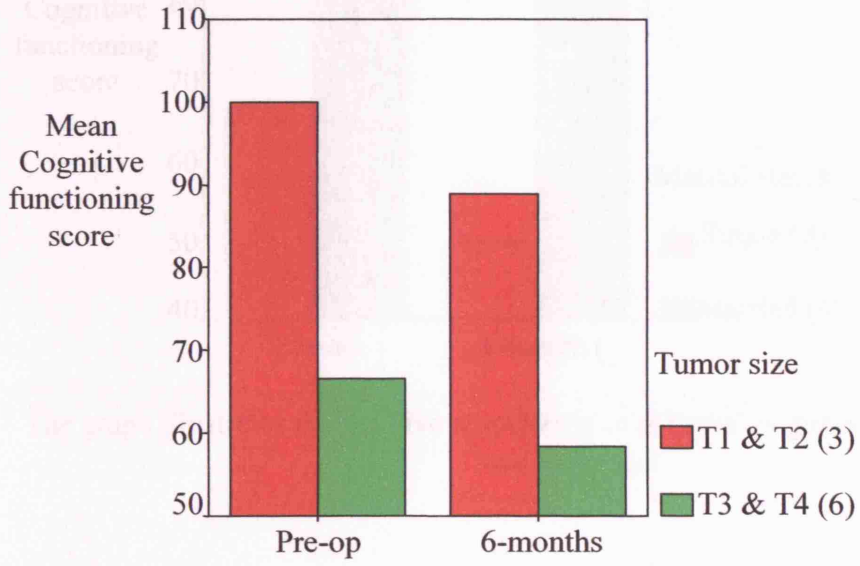
Figure 2.4.2.9: EORTC-C30 domains significantly changed with time



The correlation of the patients' characteristics with the EORTC-C30 domains was tested by the Pearson correlation test for descriptive purposes only (figures 2.4.2.10-A,B,C). At the preoperative time, there was a significant negative association between the tumour size and cognitive functioning scores (r = 0.706; p = 0.034), where 5 out of 6 patients with T_3 & T_4 scored $\leq 67\%$ compared to 3 patients with T_1 & T_2 who scored 100%. Also, the tumour size positively correlated to fatigue scores (r = 0.766; p = 0.016) at the preoperative time, where 5 out of 6 patients with T_3 & T_4 cancers scored $> 33\%$ compared to the 3 patients with T_1 & T_2 cancers who scored $\leq 33\%$. Also, at the 6-months time tumour size was positively correlated to the fatigue score (r = 0.704; p = 0.034), where 4 out of 6 patients with T_3 & T_4 scored $< 67\%$ compared to 3 patients with T_1 & T_2 who scored ≥ 67. There was an association between the patient's marital status and cognitive functioning scores at the postoperative time (r = 0.693; p = 0.038),

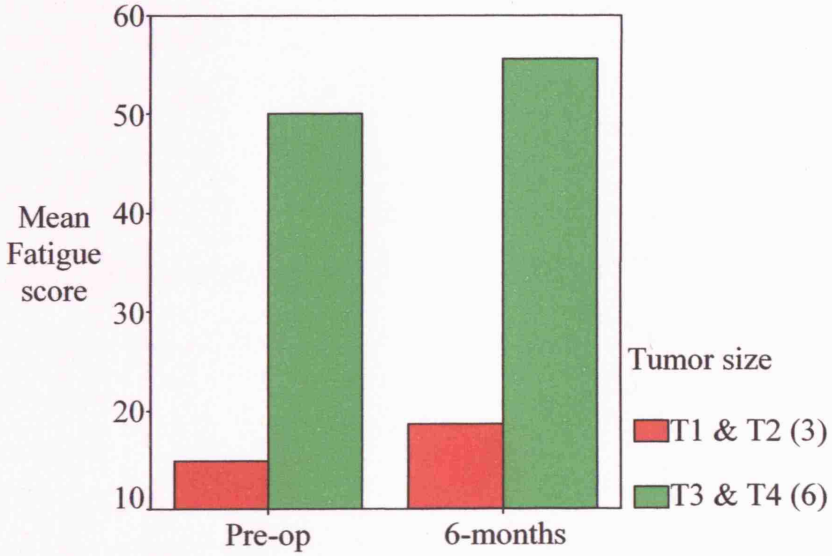
where 4 out of 5 single patients scored < 67% compared to 4 married patients who scored ≥ 67%.

Figure 2.4.2.10(A): EORTC-C30 domains significantly correlated with tumour size



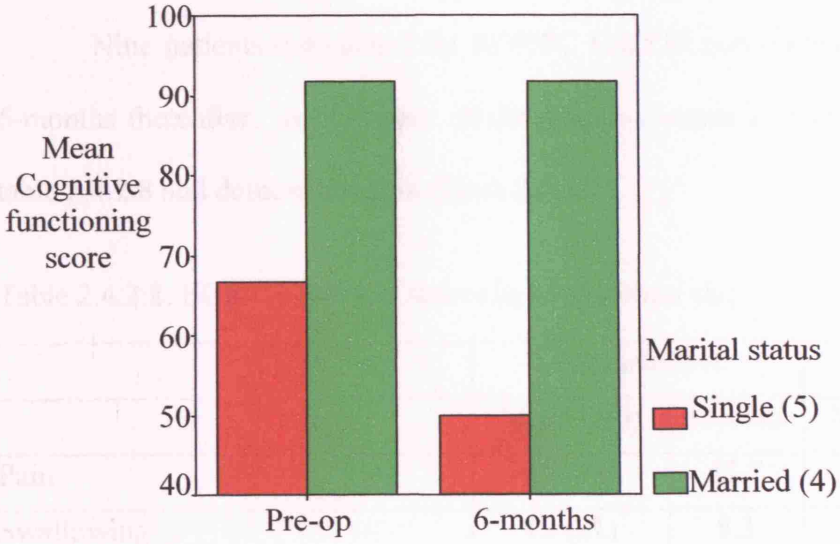
The graph illustrates the negative association of patients' cognitive functioning scores and the size of the tumour.

Figure 2.4.2.10(B): EORTC-C30 domains significantly correlated with tumour size



The graph illustrates the positive association of patients' fatigue scores and the size of the tumour.

Figure 2.4.2.10(C): EORTC-C30 domains significantly correlated with marital status



The graph illustrates the positive association of patients' cognitive functioning scores and marriage.

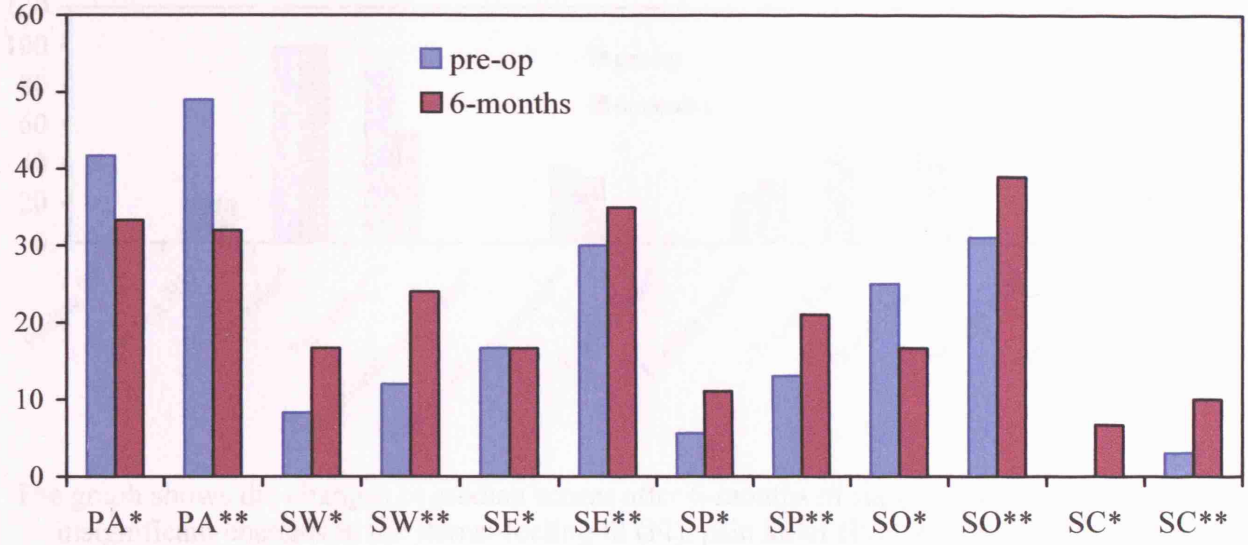
2.4.2.5 The EORTC H&N35 questionnaire

Nine patients completed the EORTC H&N35 questionnaire preoperatively and 6-months thereafter. A summary of the domains scores in both times is presented in table 2.4.2.8 and demonstrated in figure 2.4.2.11.

Table 2.4.2.8: EORTC H&N35 scores in longitudinal study

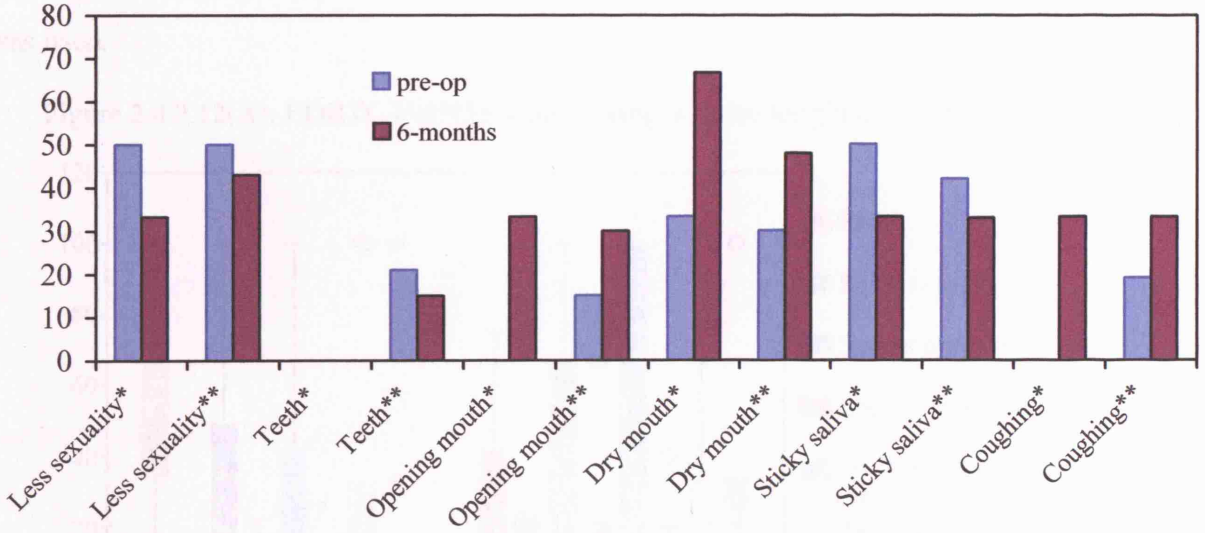
	Pre-operative		6-months	
	Mean (SD)	Median	Mean (SD)	Median
Pain	49 (22)	41.7	32 (26)	33.3
Swallowing	12 (21)	8.3	24 (30)	16.7
Senses problems	30 (36)	16.7	35 (43)	16.7
Speech problems	13 (19)	5.6	21 (27)	11.1
Trouble with social eating	31 (34)	25.0	39 (47)	16.7
Trouble with social contact	3 (5)	.00	10 (13)	6.7
Less sexuality	50 (46)	49.8	43 (38)	33.3
Teeth	21 (35)	.00	15 (24)	.00
Opening mouth	15 (34)	.00	30 (31)	33.3
Dry mouth	30 (31)	33.3	48 (34)	66.7
Sticky saliva	42 (39)	50.0	33 (37)	33.3
Coughing	19 (24)	.00	33 (33)	33.3
Felt ill	22 (33)	.00	22 (37)	.00
Pain killers	88 (35)	100	56 (53)	100
Nutritional supplements	38 (52)	.00	33 (50)	.00
Feeding tube	25 (46)	.00	33 (50)	.00
Weight loss	50 (54)	50	11 (33)	.00
Weight gain	.00	.00	33 (50)	.00

Figure 2.4.2.11(A): EORTC H&N35 scores in longitudinal study
*Median score - **Mean score



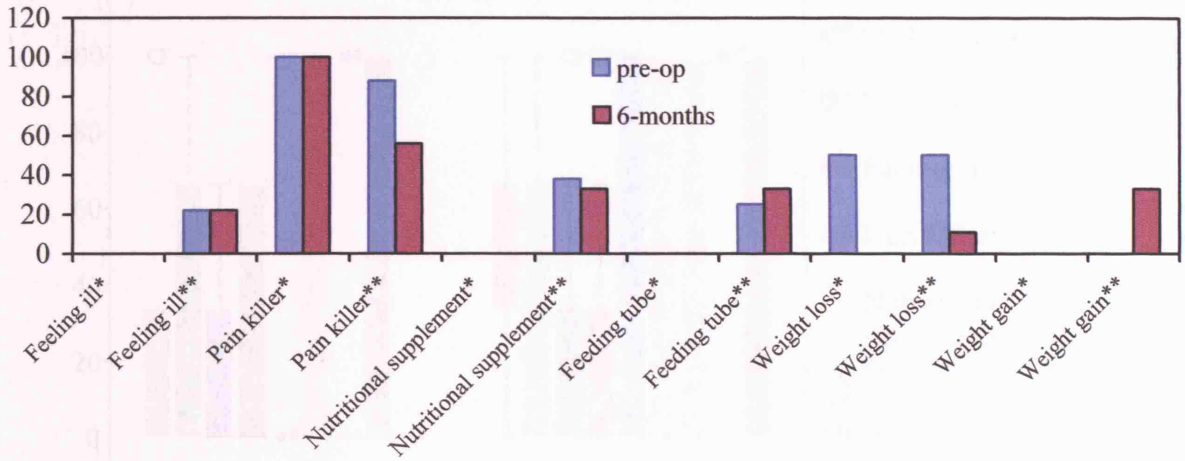
The graph shows the changes in patients' scores after 6-months of surgery. Pain (PA) scores decreased; swallowing (SW), speech problems (SP) and trouble with social contact (SC) increased; senses problems (SE) and trouble with social eating (SO) did not change.

Figure 2.4.2.11(B): EORTC H&N35 scores in longitudinal study
* Median score - ** Mean score



The graph shows the changes in patients' scores after 6-months of surgery. Sticky saliva (SS) and less sexuality (SX) scores improved after 6-months. Coughing (CO), dry mouth (DR) and opening mouth (OM) scores increased after 6-months. Teeth (TE) scores did not change.

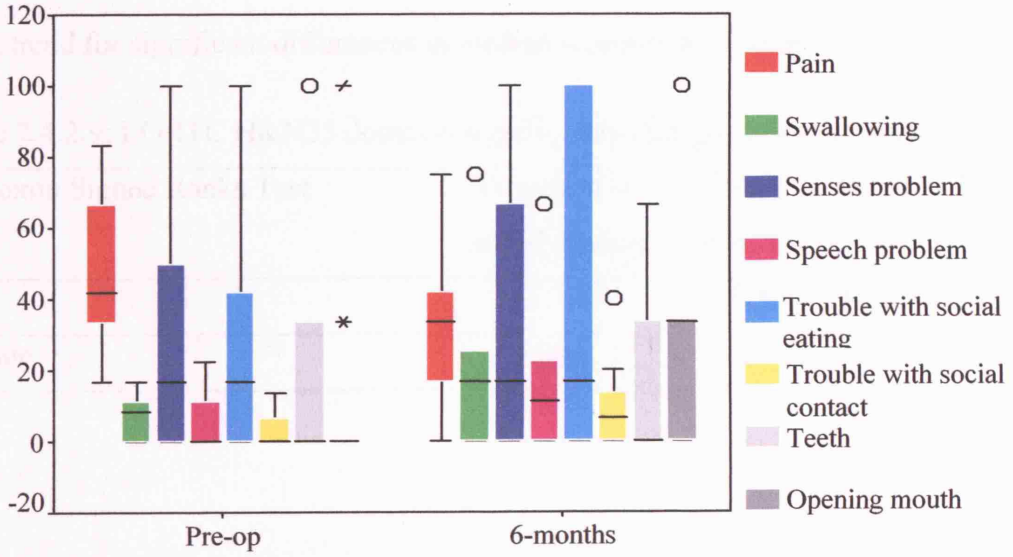
Figure 2.4.2.11(C): EORTC H&N35 scores in longitudinal study
* Meadian score - ** Mean score



The graph shows the changes in median scores after 6-months of surgery. There are insignificant changes in the items: feeling ill (FI), pain killer (PK), nutritional supplements (NU), feeding tube (FE), and weight gain (WG); except for weight loss (WL) where it improved after 6-months.

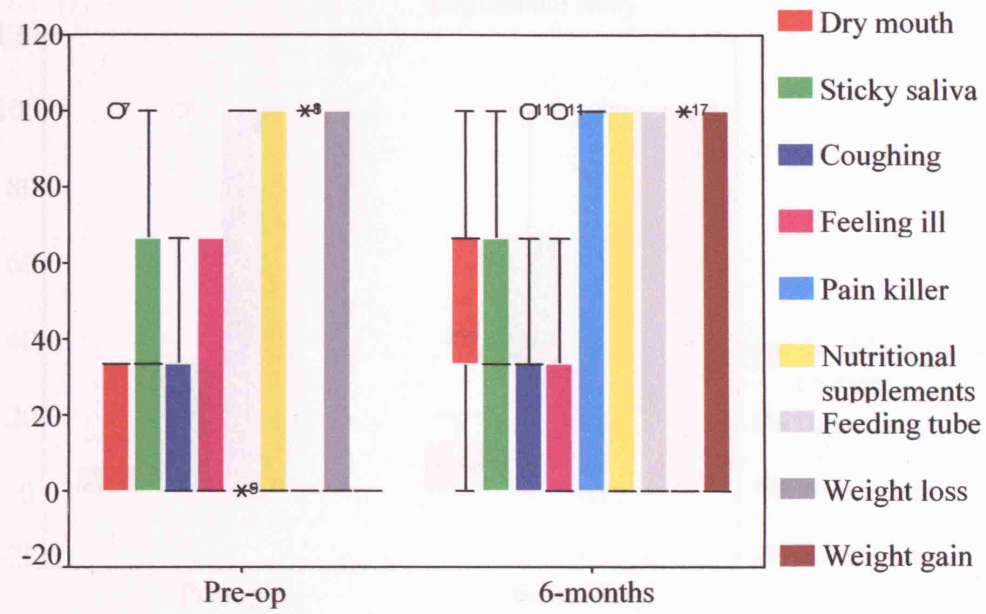
The changes in the domains scores are demonstrated in figure 2.4.2.12(A&B). For a significant difference between the patients' median score for each domain between the preoperative and 6-months post operative time, the Wilcox sign rank test was used.

Figure 2.4.2.12(A): EORTC H&N35 scores changes in the longitudinal study



The graph demonstrates differences in median scores for pain (PA), swallowing (SW), senses problems (SE), speech problems (SP), troubles with social eating (SO), trouble with social contact (SC), teeth (TE), and opening mouth (OM) between the preoperative time and the 6-months time.

Figure 2.4.2.12(B): EORTC H&N35 scores changes in the longitudinal study



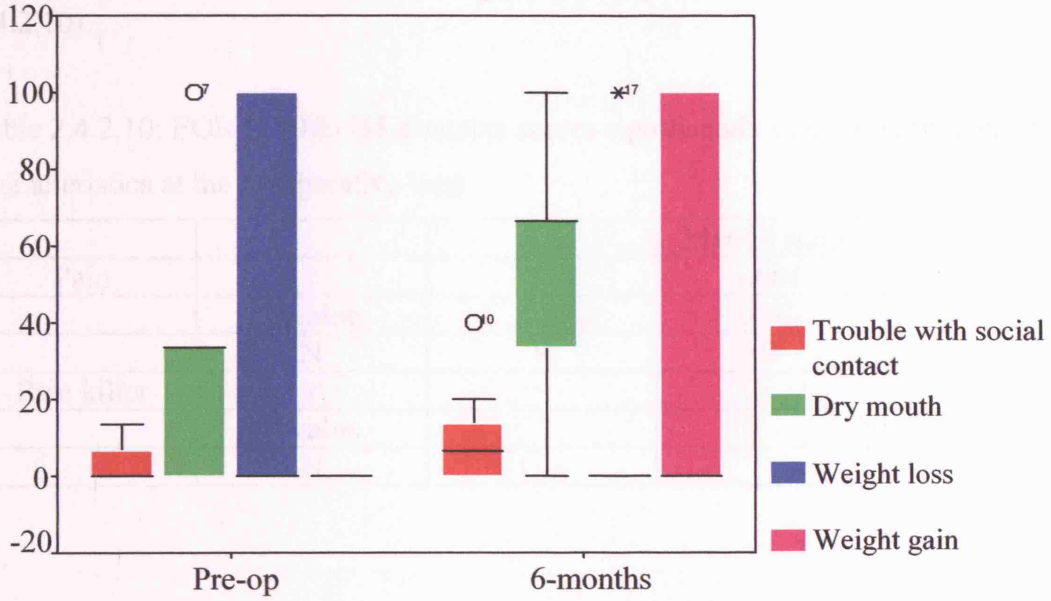
The graph demonstrates differences in median scores for dry mouth (DR), sticky saliva (SS), coughing (CO), feeling ill (FI), pain killers (PK), nutritional supplements (NU), weight loss (WL), and weight gain (WG) between the preoperative time and the 6-months time.

The less sexuality domain is omitted from the graph because it was answered only by 5 patients and will disturb other domains if included as the others were completed by all the 9 patients. The Wilcoxon Signed Ranks Test was not significant for all domains; however, 4 domains listed in table 2.4.2.9 (figure 2.4.2.13) show a weak trend for significant differences in median scores between the two times.

Table 2.4.2.9: EORTC H&N35 domains significantly changed in the longitudinal study

Wilcoxon Signed Ranks Test	Trouble with social contact	Dry mouth	Weight loss	Weight gain
Z	-1.725	-1.890	-1.732	-1.732
P-value	.084	.059	.083	.083

Figure 2.4.2.13: EORTC H&N35 domains with tendency for significant change in the longitudinal study



For correlation of those domains with a tendency for significant change over time and their patients' characteristics the Pearson correlation test was applied. The troubles with social contact score was significantly associated with reconstruction type ($r = -.803$; $N = 9$; $p = 0.009$) this is due to one patient with primary closure scored >13% compared to one patient out of eight with free vascular flap who scored >13%. However, the value of this significance is undermined because of the small number of patients.

For association of the domains scores and patients' characteristics the Pearson correlation test was applied again; however, this was for descriptive purposes only due to the small number of patients.

At the preoperative time pain was negatively associated with age where 3 patients (3/4) aged more than 60 years who scored < 42% compared to 5 patients (5/5) aged less than 60 years scored ≥ 42%; also, pain was associated with marital status where 4 married patients (4/4) scored < 50 compared to 4 single patients (4/5) scored ≥ 50. Pain killer score was correlated to tumour size where 4 patients (4/6) with T_3&T_4

scored 100%, compared to one patient (1/3) with T_1&T_2 who scored 100% (table 2.4.2.10).

Table 2.4.2.10: EORTC H&N35 domains scores significantly correlated with patients' characteristics at the preoperative time

		Age	Marital status	T. size
Pain	r	-.775	-.684	
	P-value	.014	.042	
	N	9	9	
Pain killer	r			.756
	P-value			.018
	N			9

2.4.3 Anxiety correlation with other HRQOL scores

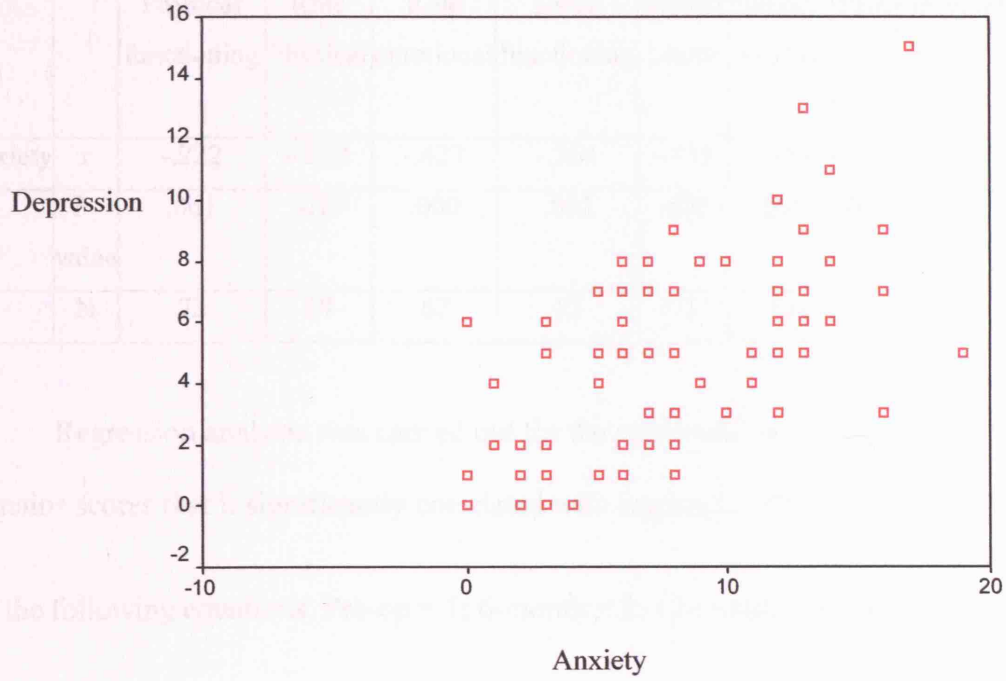
The study aimed to examine the hypothesis that that high anxiety scores predicted poorer quality of life scores. The anxiety raw scores from the HAD scale were plotted against depression scores from the HADS and HRQOL domain scores in the other questionnaire and tested with the Pearson Correlation test for significant association. If correlation was significant, the predictability equation for that domain by anxiety will be formulated after adjustment for the time of management using multiple regression analysis.

The patients' sample for this correlation study included all the 19 patients completed the questionnaires in the preoperative time, 8 patients at 6-months, 13 patients at 12-months and 33 patients at 24-months times. Patients at the 3 months time (10) and some of the 6-months time (9) were excluded from the sample; this is because in multiple regression analysis patients included only once. Significant correlations at p-value of 0.01 were further tested by regression analysis to find out the predictability of anxiety to depression and other HRQOL domains in other questionnaires when adjusted for times of the patient' management (pre-op, 6-months, 12-months, 24-months).

2.4.3.1 Anxiety correlation with depression:

Anxiety scores were positively associated with depression scores from the HADS in this sample of patients ($r = 0.619$; $N = 73$; $p = 0.000$).

Figure 2.4.3.1: Correlation of anxiety and depression scores



Multiple regression analysis showed that the predictability of anxiety to depression was significant when adjusted for times of patients' management (appendix VIII - table 2.4.3.1).

- Predicted Depression score = - .0032 + (.475 x Time†) + (.442 x Anxiety score)

† Pre-op = 1; 6-months = 2; 12-months = 3; 24-months = 4

2.4.3.2 Anxiety correlation with SF-36 scores:

The Pearson correlation test showed that anxiety scores were significantly correlated to all domains scores of the SF-36 at 1% level (table 2.4.3.2) except for the physical functioning (PF), general health perception (GH) and change in health (CH).

Table 2.4.3.2: Correlation of anxiety and SF-36 domains scores

		Physical functioning	Role Physical	Role emotional	Social functioning	Mental health	Energy/ vitality	Pain	General health	Change in health
Anxiety	r	-.222	-.310	-.427	-.364	-.755	-.445	-.308	-.294	.191
	P-value	.061	.010	.000	.002	.000	.000	.008	.012	.113
	N	72	69	67	73	71	70	73	72	70

Regression analysis was carried out for the predictability of anxiety scores to domains scores that it significantly correlated with (appendix VIII - table 2.4.3.3).

(In the following equations, Pre-op = 1; 6-month = 2; 12-month = 3; 24-month = 4)

- Predicted physical problems (RP) score = 81.89 – (2.21 x Time) – (2.9 x Anxiety score)

- Predicted emotional problems (RE) score = 86.77+ (0.93 x Time) - (4 x Anxiety score)

- Predicted social function score = 82.31 – (0.40 x Time) - (2.19 x Anxiety score)

- Predicted mental health score = 88.45+ (1.8 x Time) - (3.36 x Anxiety score)

- Predicted energy & vitality score = 82.08 - (3.47 x Time) - (2.29 x Anxiety score)

- Predicted pain score = 84.43 - (1.14 x Time) - (1.85 x Anxiety score)

- Predicted general health perception score = 84.64 - (4.94 x Time) - (1.9 x Anxiety score)

2.4.3.3 Anxiety correlation with EORTC-C30 domains scores:

The Pearson Correlation test showed that anxiety scores significantly correlated with most of the domains scores measured in the EORTC-C30 questionnaire (table 2.4.3.4).

Table 2.4.3.4: Pearson Correlation Test for Anxiety and the EORTC-C30 domains scores

		Global health status	Physical functioning	Role functioning	Emotional functioning	Cognitive functioning	Social functioning	Fatigue
Anxiety	r	-.472	-.231	-.300	-.742	-.397	-.327	.420
	P-value	.000	.051	.010	.000	.001	.005	.000
	N	72	72	72	72	72	72	72

		Nausea/ vomiting	Pain	Dyspnoea	Insomnia	Appetite loss	Constipation	Diarrhea	Financial difficulties
Anxiety	r	.345	.407	.226	.289	.385	.158	.270	.311
	P-value	.003	.000	.060	.014	.001	.190	.023	.009
	N	72	72	70	72	72	71	71	70

Regression analysis was applied for the predictability of the anxiety score for the domains scores that it significantly correlated with (appendix VIII - table 2.4.3.5).

(In the following equations; Pre-op = 1; 6-month = 2; 12-month = 3; 24-month = 4)

- Predicted global health status score = 79.57 + (0.32 x Time) - (2.42 x Anxiety score)

- Predicted role functioning score = 97.68 - (3.86 x Time) - (2.07 x Anxiety score)

- Predicted emotional functioning score = 96.27 - (0.10 x Time) - (3.61 x Anxiety score)

- Predicted cognitive functioning score = 92.25 + (0.74 x Time) - (2.01 x Anxiety score)

- Predicted social functioning score = 101.48 - (4.0 x Time) - (2.39 x Anxiety score)

- Predicted fatigue score = 9.33 + (2.78 x Time) + (2.48 x Anxiety score)

- Predicted nausea & vomiting score = -0.46 - (0.29 x Time) + (1.47 x Anxiety score)

- Predicted pain score = 7.74 + (0.19 x Time) + (2.74 x Anxiety score)

- Predicted insomnia score = 11.35 + (4.02 x Time) + (2.55 x Anxiety score)

- Predicted appetite loss score = 19.80 - (3.30 x Time) + (2.47 x Anxiety score)

- Predicted financial difficulties score = 8.19 - (1.55 x Time) + (2.09 x Anxiety score)

2.4.3.4 Anxiety correlation with QLQ-H&N35 domains scores:

Anxiety scores were significantly correlated with many domains scores from the QLQ-H&N35 when tested by the Pearson correlation test (table 2.4.3.6).

Table 2.4.3.6: Pearson Correlation Test for anxiety and EORTC H&N35 domains scores

		Pain	Speech problem	Trouble with social eating	Trouble with social contact	Less sexuality
Anxiety	r	.277	.375	.301	.464	.492
	P-value	.019	.001	.011	.000	.000
	N	72	70	70	71	61

		Teeth	Mouth opening	Coughing	Feeling Ill	Pain Killer	Weight loss
Anxiety	r	.298	.285	.356	.436	.321	.287
	P-value	.013	.015	.002	.000	.006	.016
	N	69	72	70	70	71	70

Regression analysis was carried out for the predictability of anxiety scores to the domains scores they correlated with (appendix VIII - table 2.4.3.7).

(In the following equations, Pre-op = 1; 6-month = 2; 12-month = 3; 24-month = 4)

- Predicted pain score = 40.71 - (7.04 x Time) + (1.28 x Anxiety score)

- Predicted speech problem score = -3.40 + (2.69 x Time) + (2.0 x Anxiety score)

- Predicted trouble with social eating score = 18.44 - (1.68 x Time) + (1.82 x Anxiety score)

- Predicted trouble with social contact score = -13.5 + (3.06 x Time) + (2.5 x Anxiety score)

- Predicted less sexuality score = 6.8 + (0.36 x Time) + (4.03 x Anxiety score)

- Predicted teeth score = 7.69 - (0.42 x Time) + (1.98 x Anxiety score)

- Predicted opening mouth score = 1.36 + (4.29 x Time) + (2.54 x Anxiety score)

- Predicted coughing score = 1.28 + (2.54 x Time) + (1.94 x Anxiety score)

- Predicted felt ill score = 2.44 - (1.7 x Time) + (3.03 x Anxiety score)

- Predicted pain killers score = 33.14 - (2.21 x Time) + (3.23 x Anxiety score)

- Predicted weight loss score = 23.19 - (6.84 x Time) + (1.92 x Anxiety score)

2.4.4 SF-36 domains association with EORTC-C30 domains

The SF-36 is a global health related quality of life questionnaire and the EORTC-C30 is a cancer specific health related quality of life questionnaire. Both have been used in cancer patients; however, patients needed to answer many questions if given both instruments especially when complemented with site specific instruments, which may reduce compliance. Also, the cancer specific questionnaires are not made for high risk cancer patients. Therefore, using the SF-36 questionnaire on cancer patients and seeing how it correlates to domains in the cancer specific questionnaire will help in describing HRQOL change when patients do develop cancer.

Except for change in health, the Pearson correlation test found a significant correlation between all the SF-36 domains and its corresponding items in the EORTC-C30 ($p = 0.000$). This correlation has been reported previously by Rogers et al (2000). The scatter plots in plate 2 (appendix IX) demonstrate the relationship of the domains in the SF-36 and the EORTC-C30. It is clear that a positive association is present between the general health status (GH) and the global health status (QL2); between the physical function (PF) and the physical functioning (PF2); between the social functioning domain in both questionnaires. A negative association was present between the energy and vitality domain (EV) and the fatigue domain (FA); and between the pain scores measured in the SF-36 and the pain scores measured in the EORTC-C30. This pattern is due to the way the questionnaire was constructed. In the SF-36 the higher the score value the better the outcome; in the EORTC-C30 this method of scoring is only for the functioning scales and it is the opposite in the symptom scales (i.e. the lower the scale the better the outcome).

Although, the mental health scores (MH) positively associated with the cognitive functioning score (CF), the pattern in the graph was less clear. The same can

be said for the association between the role limitation due to emotional problems (RE) and the emotional functioning (EF), and between the role limitations due to physical problems (RP) and the role functioning (RF2). The change in health item in the SF-36 questionnaire has no comparable item in the EORTC-C30 questionnaire.

2.5 Discussion

The importance of the quality of life assessment in the management of cancer patients and the evaluation of different therapeutic interventions is now well recognised. HRQOL in head and neck cancer patients do change throughout the course of treatment from the preoperative level, but researches have found that patients regain a similar level to their preoperative level in most of the HRQOL domains after one year. Furthermore, oral and pharyngeal cancers are considered highly traumatic psychologically; this is due to the facial disfigurement and functional impairment that may result from the cancer and its treatment. Generally, the mean anxiety score decreases with time during the postoperative period and depression increases; however, in this study anxiety was found to be significantly correlated with many of the HRQOL domains.

Originally the study design was to look for the correlation between the changes in level of patients' satisfaction with informational support via the educational intervention and patients' level of anxiety and HRQOL. However, results from the previous study in chapter 1 revealed that informational supports to oral and pharyngeal cancer patients at the maxillofacial unit were adequate, and additional educational intervention would require a large number of patients to produce significant improvement in patients' satisfaction with informational support. Recognising these difficulties, it was decided to do an observational (longitudinal and a cross sectional) study for the assessment of patients' anxiety and HRQOL.

In the cross sectional study, patients were recruited in successive independent samples from different times of management (preoperative time, and postoperatively at 3-months, 6-months, 12-months and 24-months times). This study would give a more comprehensive view as it includes long term follow up patients where the risk of

recurrence gradually decreases and patients are expected to be better adapted to routine life.

Successive independent sampling design, allows studying the changes of attitude and behaviour of oral and pharyngeal cancer patients over time; however, it does not allow for inferring how individual patients have changed over time. This design adequately served the purpose of this part of study (i.e. describes the anxiety and HRQOL at different times of treatment and the correlation between the two). A prerequisite to this type of study is that patients are drawn from a population that is equally representative of the population. This was achieved by having patients from one unit, treated by the same team of doctors and received the standard postoperative care available. Variation in site and type of cancer and treatment received was moderated by increasing the sample size.

Some of the preoperative patients were further followed-up for 6-months. This group was considered as a longitudinal study and analysed accordingly. The longitudinal design allowed assessment of anxiety and HRQOL changes in oral and pharyngeal cancer patients over time and the association between HRQOL domains scores and anxiety scores or patients demographics; however, this does not imply causation. A major threat to a longitudinal design study is the attrition of data due to patients' drop-out (Aaronson 1991). This is important because usually patients who drop out are either physically very ill or have died, and both are very likely to have a poorer quality of life than others are. Rogers at al (1998) reported a 50% drop-out at one year follow up (Rogers et al. 1998a), while Hammerlid et al (1999) reported a 27% dropout at one year (Hammerlid et al. 1999a). Furthermore, the use of self completed questionnaires, has contributed to the problem. Therefore, the results in the longitudinal study are likely to underestimate symptoms domains and overestimate functional domains of anxiety and HRQOL.

The HADS is a simple and easy questionnaire to administer and to complete (Bergelt 2005); it is designed to assess the patient's anxiety and depression on a weekly bases. It has been documented for use in medical and non-medical patients; and recommended for use in cancer patients as it is not influenced by somatic symptoms and it assesses depression in the meaning of loss of interest, a more relevant approach to the cancer population. The SF-36 and the EORTC core and site specific quality of life questionnaires are more comprehensive instruments (Bergelt 2005) and have been used previously in the head and neck cancer population with a validated psychometric property; however, they demand more time and co-operation from patients, and only assess patients' functions and symptoms on a monthly bases. The literature has recognised significant changes from the preoperative time in domains scores included in these instruments are recognisable at 3-months, 6-months and 12-months postoperatively.

In this part of the study, the patients' demographics and representations were comparable to the oral and pharyngeal cancer population; only 5 patients (6 %) were excluded from the study due to difficulties with reading and writing English. Seventy nine (79) patients offered to participate and 75 complied (95%). It is noteworthy that in the longitudinal part of the study 8 patients were lost at the 6-months follow-up due to death (3 patients), recurrence (2 patients) and ill health (3 patients); this indicates that the true prevalence of physical and psychological morbidity is underestimated.

The following section will discuss the finding for the assessment of patients' anxiety and depression using HADS, as well as their HRQOL using SF36, EORTC-C30 and EORTC H&N35.

2.5.1 The HADS

One of the main purposes of the HADS is to screen medical patients for psychological disturbances, however, it does not allow a definite diagnosis; therefore it gives a dimensional rather than categorical statement of mood. Although a categorical viewpoint demonstrates that symptoms for a disorder were bimodally distributed, and provided sufficient evidence that a disorder is qualitatively different from similar symptoms experienced at a lower level.

The scoring: The use of the cut-off point in the HADS allows for identifying individuals likely to be anxious or depressed; however, the questionnaire identify-ability depends on the instrument specificity and sensitivity. In general, increasing the cut-off point increases also the specificity while reducing the sensitivity. In this study we used a low cut-off point because it was necessary to identify depressed and anxious cases as well as cases likely to be so. The cut-off point of 8+ was recommended by Zigmond and Snaith (1983) for possible caseness of anxiety and depression, and was found to provide an optimal balance between sensitivity and specificity (Bjelland et al. 2002, Zigmond et al. 1983).

2.5.1.1 Anxiety results

The HADS displayed levels of anxiety at different times of disease management similar to those reported in previous studies (Hammerlid et al. 1999a, shepherd et al. 2004). Hammerlid et al (1999) reported the highest number of patients with caseness for anxiety at the preoperative time (32%) with a gradual decline of up to one year (20%). This decline was reported to continue in patients after 3 years follow-up (Hammerlid et al. 2001a). The percentage of patients with caseness for anxiety in this study was higher in all times than the reference sample (Hammerlid et al. 1999a); however, corresponds well with the lower scores in emotional functioning as reported in

the EORTC-C30 in this study. This is perhaps because all patients in this study received surgery compared to 37% patients in the Hammerlid study, and surgery is more likely to produce physical problems and facial disfigurement.

Although, the HADS was constructed not to be influenced by somatic symptoms (Johnston et al. 2000); patients reported high levels of anxiety at the preoperative and the 3-months postoperative times in the cross sectional study which gradually declined afterwards. The high anxiety level at 3-months in this study may be attributed to the medical or surgical co-morbidity that sometimes is associated with anxiety (Kogan et al. 2000), because oral and pharyngeal cancer patients are expected to endure most of the treatment side effects during this period; and patients with increased preoperative anxiety were reported to have increased anxiety levels postoperatively (de Groot et al. 1997).

In the longitudinal study, there was no significant difference between the anxiety scores at the preoperative time and 6-months after ($p = 0.14$), but there was a weak trend that patients who scored 8+ at the preoperative time would continue to score 8+ at the 6-months time ($\chi^2 = 0.058$). High anxiety levels before surgery (especially for cancer) are not unusual (Herrmann 1997), and anxiety and depression are well recognised in head and neck cancer patients before and after treatment (Hammerlid et al. 1999a, Rogers et al. 1999b). The insignificant difference in anxiety scores at the preoperative time and 6-months postoperative time have been suggested by Hammerlid et al (1999) where they found anxiety and depression levels at diagnosis also significantly predicted anxiety and depression scores at one year (Hammerlid et al. 1999a). High postoperative anxiety can be related to many factors including patient diagnosis of generalised anxiety disorder (Endler et al. 2001, Slade et al. 2001), a lack of psychosocial support or a lack of information about the present and future outcome of treatment (Walker et al. 2003), fear of recurrence, or simply due to patients going

through a difficult period adjusting to the physical side effects of treatment especially in those patients who scored 8+ (De Boer et al. 1999).

2.5.1.2 Depression results

The percentage of patients with possible depression in this study was lower than anxiety in all times and displayed another pattern; however, the difference between the different times was not statistically significant. Hammerlid et al (1999) reported similar findings for head and neck cancer patients where depression peaked at the 3-months postoperative time then gradually improved thereafter up to 1 year (Hammerlid et al. 1999a). A similar finding was reported by de Graeff et al (1999) where they found no change in mood scores between diagnosis, 6-months and the 12-months times measured by the CES-D (Centre for Epidemiologic Studies' Depression Scale) (de Graeff et al. 1999). The level of depression in post-surgical head and neck cancer patients was reported to be within the range of non-depressed range (Katz et al. 2003).

At the 24-months time, the percentage of patients with caseness for depression increased, contrary to the results from the Hammerlid at al (2001) study where depression decreased significantly from 21% at diagnosis, 19% at 1 year to 9% at 3 years postoperative (Hammerlid et al. 2001a). Depression is commonly associated with chronic symptoms or diseases (Herrmann 1997); and the surgical treatment of cancer may produce permanent changes to the patient's appearance and function. Unless these side effects are addressed early with the patient and dealt with properly, it is not unusual for patients to develop depressive symptoms (Katz et al. 2003). Moreover, the percentage of long term follow-up patients with possible depression in this study (24-months time) included patients from 18-months up to 5 years postoperative, while in the Hammerlid et al (2001) study the percentage was specific to patients at 3-years postoperative and only 39% of the patients received surgical treatment (Hammerlid et

al. 2001a). In addition, more recently Petruson and Hammerlid (2003) in a study of the effect of psychosocial intervention on head and neck cancer patients reported depressive symptoms by 28% at diagnosis and 21% at 3-years postoperative in the control group and a similar number (26% vs 20%) in the intervention group (Petruson et al. 2003).

It is possible that the HADS is not appropriate for elderly people, as it may reflect physical distress, and that other scales (e.g. Cancer-specific distress questionnaire) may be more appropriate.

2.5.1.3 Influential factors

The influence of surgical treatment on the HADS scores is inconsistent. When treatment intention is curative and results in the improvement of somatic symptoms such as in knee replacement surgery, the HADS scores decreased (Drewett et al. 1992). However, if treatment is to manage the consequences of a disease such as coronary artery bypass surgery or for investigational purposes such as breast biopsy, the HADS scores increased (Al-Rizzeh et al. 2004, Lampic et al. 2001). Surgical treatments for head and neck cancer are commonly for curative intention; nonetheless, these are comorbid with physical effects such as fatigue, facial disfigurement and speech problems which may in turn cause psychological problems. The following section will shed light on the most important related factors:

I. Tumour size factor: at the preoperative time, there was an indication for an association between large tumours (T_3&T_4) and caseness for anxiety. This result is consistent with Kugaya et al (1999) findings of significant correlation between advanced time cancer and psychological distress in newly diagnosed head and neck cancer patients. It has been suggested that anxiety is more associated with physical symptoms and depression more with compliance after treatment (Herrmann 1997). This association is supported in this study by the weak tendency for patients with

posterior/medial soft tissue resection in relation to the teeth to report HADS scores 8+ (both anxiety and depression) at the 6-months postoperative time.

Large tumours demand more aggressive surgery and this is likely to result in more physical problems and patients needing more time for rehabilitation. Large head and neck cancers consistently scored more frequently as possible cases of psychiatric morbidity than patients with small cancers at all times of treatment for up to one year, and showed stronger correlation between depression and type III & IV cancers (Hammerlid et al. 1998, Hammerlid et al. 1999a). De Graeff et al (1999) found oral and pharyngeal cancer patients who received surgery followed by radiotherapy scored worse in physical symptoms than patients treated with surgery alone; and the level of depressive symptoms was high before and after treatment (de Graeff et al. 1999). In this study, there was a significant association between the depression scores and the level of neck dissection ($r = 0.026$) at the postoperative times; where neck dissection level IV-V tended to have higher depression scores. Also, at the 24-months time there was a trend for an association between high depression scores 8+ and patients who received loss of continuity bone resection (maxillectomy or mandibulectomy).

II. Patient's age factor: High HADS-anxiety scores are more common in patients aged <59 years than in patients aged 60-70 years; while high depression scores are more common in patients aged 50-59 years than in the younger group aged <30 years (Herrmann 1997). In this study, there was a strong association between the HADS-Anxiety raw scores and patients age ($r = 0.008$); where younger patients tended to have higher scores and regression analysis showed that age was a significant independent predictor for anxiety when adjusted for gender and management time ($r = 0.005$). This is in line with Hammerlid et al (2001) study where they found a significantly higher anxiety prevalence in patients aged <65 years compared to patients aged >65 years at diagnosis, one year and three years postoperatively (Hammerlid et al. 2001a).

Moreover, the result shows a trend for patients aged less than 60 years to have scores 8+ in the HADS-Depression scale at the 12-months time. A similar association between age and HADS sub-scales was reported by Fossa et al (2002) where they found HADS-depression scores increased with age whereas HADS-anxiety decreased (Fossa et al. 2002). However, other studies used the CES-Depression scale on head and neck cancer patients and found no relation between the patient's age and depression before and after treatment (de Graeff et al. 1999, Kugaya et al. 1999). Nevertheless, anxiety in older adult patients must be interpreted with caution. This is because of the physiologic age-related changes; the coexistence of anxiety and other psychological problems including depression which is more common, as well as the increased incidence of chronic medical illness with age. The majority of the present assessment instruments are designed for young adults (Kogan et al. 2000).

III. Patient's gender factor: It was reported that females had higher score in the HADS-anxiety subscale than males but not in the depression subscale (Herrmann 1997). In this study, there was an indication for female patients to have higher anxiety scores than male patients ($r = 0.054$) but not for depression, and regression analysis showed that gender is a significant independent predictor for anxiety even after adjustment for age and management time ($r = 0.035$). This finding is supported by the Hammerlid et al (1999) study which found significantly worse scores for female compared to male patients in HADS-Anxiety scores at diagnosis and throughout the 1-year postoperative, but insignificant change for HADS-Depression (Hammerlid et al. 1999a). Two other studies on head and neck cancer patients used the CES-Depression scale and found no effect for gender on depression (de Graeff et al. 2000, Kugaya et al. 1999).

Head and neck cancer surgery may profoundly affect patient's quality of life due to facial disfigurement associated with treatment (Dropkin 1999), and the difficulty most frequently reported in facially disfigured people is social anxiety associated with

phobic avoidance, whereas depression is considerably less common (Newell et al. 2000).

The relationship between gender, facial disfigurement and psychosocial adjustment is complicated. A cross sectional HRQOL study by Hassanein et al (2001) on 68 patients with oral cancer 6-months or more after surgery found facial disfigurement to be a significant problem for female patients (Hassanein et al. 2001). Katz et al (2003) in a cross sectional study looked at the relationship of facial disfigurement, gender and psychosocial adjustment in 82 head and neck cancer patients. They found a significant correlation between disfigurement and depression, with high depression scores in female patients, however, patients overall demonstrated a high level of adjustment (Katz et al. 2003). They did not assess anxiety in their study and used the CES-Depression scale to measure depression which measures the general mood stats, compared to HADS-Depression that focuses mainly on loss of interest in pleasure-seeking activities, but not other components of depression such as low self esteem, and hopelessness (Mykletun et al. 2001). It seems that woman have higher depression scores which may be a reflection of social anxiety, however, the interaction between anxiety and depression and facial disfigurement is complex and warrants further investigation recognising other components of depression and social anxiety.

2.5.2 HRQOL assessment

The gradual improvements in quality of life at the preoperative level has been reported in previous studies (Rogers et al. 1999c, Schliephake et al. 1996). A prospective study on head and neck cancer patients treated with radiotherapy alone reported similar improvements, however, the problem of dry mouth increased and about one third of patients' continued to complain of pain, eating and drinking problems at one year (Hammerlid et al. 1997). Radiotherapy is known for certain side effects

including dry mouth; this is due to the irreversible damage occurring in the salivary glands in the line of radiation. Reduction in salivary flow is a major factor in eating and drinking related problems; therefore an increase in eating and drinking problems is expected in patients who receive radiotherapy. Also, combined treatment (surgery + radiotherapy) is reported to result in greater pain relief compared to radiotherapy alone (Deleyiannis et al. 1997).

Rogers at al (1999) reported a great similarity between patients HRQOL scores at one year and scores for the five years survivors suggesting that the one year outcomes are good long term predictors. However, a small number of patients continue to experience severe problems in emotional and cognitive functioning, chewing related functions, and disfigurement (Rogers et al. 1999c). In this study, the SF-36 and EORTC-C30 scores at the 12-months time and 18-months or more time were comparable. However, there was also deterioration in scores for sexuality, pain killer, sticky saliva, insomnia and appetite loss, and improvement in speech, social eating and dry mouth. Similar results were reported after three years follow-up for head and neck cancer patients treated largely with radiotherapy where most patients' scores did not significantly differ from their scores at one year but were significantly better than at their preoperative scores, even comparable to the Swedish norms sample scores for general health and mental health in the EORTC-C30 and SF-36. However, some of the EORTC H&N35 domains scores such as problems with teeth, dry mouth and senses were significantly worse for head and neck cancer patients than the norms (Hammerlid et al. 2001b, Hammerlid et al. 2001a). Furthermore, a longitudinal study on laryngeal cancer patients found no significant change in most of HRQOL domains scores between 1 and 5 years measured in the EORTC-C30 and H&N35; however, physical functioning, role functioning, dry mouth, swallowing and social eating all deteriorated with time (Nordgren et al. 2003).

Social support contributes greatly to quality of life in head and neck cancer patients (Baker 1992); and with continuous motivation and support it was possible to demonstrate a good quality of life in patients with significant functional impairment (Finizia et al. 1998, Ruhl et al. 1997). Psychosocial support would have its most effect at the time when patients are challenged by the treatment side effects; therefore, significant differences are expected at the 3-months or 6-months time. In this study, there was some indication that patients received good psychosocial support. In the SF-36 questionnaire, at the 3-months time there were higher mean scores for physical functioning, role emotional, mental health and general health status than at the preoperative time although the differences were not significant statistically. At 6-months, the scores for 7 out of the 8 domains were higher than at the preoperative time. Also, in the EORTC-C30 there was a trend for a significant high score for emotional functioning compared to the preoperative score; this is consistent with the reduction of anxiety score at the 6-months time.

In the longitudinal study most of the SF-36 domains scores were similar or worse than the preoperative values, except for mental and social health where they showed a tendency for statistically significant improvement at the 6-months time from the preoperative time. In the EORTC-C30 pain score significantly improved while insomnia score significantly worsened. None of the symptoms/items scales in the EORTC H&N35 show significant changes over the six months follow up period.

Pain improvement after surgery is constantly reported in many HRQOL studies, however, the high SF-36 scores especially at the 6-months time and improvement in anxiety and emotional functioning scores (EORTC-C30) may indicate that patients received a good psychosocial support during rehabilitation in the unit and at home. The decline of the SF-36 scores at 12-months to preoperative values could be because the scores were higher at 6-months than expected; or the lack of continuity of successful

psychosocial support; this may be related to staff ability/availability or the system, as follow-up appointments are less frequent after 6-months of treatment. The expression of these changes in the SF-36 but not in the EORTC-C30 questionnaire may be related to the quality of life aspects the questionnaires target; the SF-36 is a global health questionnaire while EORTC-C30 is a cancer specific questionnaire. Also, it may indicate that the support provided is non-specific, and not targeting cancer's conventional side effects such as fatigue and insomnia, or underestimating it.

2.5.3 Preoperative predictors

Preoperative predictors considered in this study were patients' age, gender, tumour size (T_1&T_2 / T_3&T_4) and neck nodes condition (+Ve or –Ve). Multiple regression analysis will consider predictability of each variable after adjusting for the others.

(I) Tumour size: Tumour size has been suggested before as one of the predictors of HRQOL scores in head and neck cancer patients (Hammerlid et al. 2001a, Rogers et al. 2000). Large tumours correlated with increased pain (Rogers et al. 1998a). Moreover, large tumours were significant predictors for worse scores in many functional problems after three years follow up (Hammerlid et al. 2001a). In this study, large tumours correlated significantly with low scores for emotional problems (RE) from the SF-36; and in the longitudinal study, patients with large tumours tended to have lower scores in emotional problems (RE), physical problems (RP) and social functioning (SF) at the preoperative time. In the EORTC-C30, patients with large tumours in the longitudinal study had significant association with increased fatigue scores at the preoperative and 6-months after times; with lower scores for cognitive functioning. However, multiple regression analysis found no effect for tumour size on the SF-36 and EORTC-C30 scores. In the EORTC H&N35 patients with large tumours

reported more problems with speech, social eating, social contact, ability to open the mouth wide and with the feeding tube; also, large tumours correlated with high scores for pain killers in the longitudinal study. However, adjustment for multiple variables in regression analysis found large tumours were associated with more problems in social eating and the feeding tube, only. Tumour size association with many HRQOL domains do not look very strong and may by related more to symptoms problems. This is perhaps because the tumour size is an indication for more aggressive treatment which can be a better predictor of quality of life (Deleyiannis et al. 1997, Rogers et al. 1998a).

(II) Neck state: Neck state and tumour stage were reported to be important predictors for long term survival (Gleich et al. 2003). The tumour stage had a direct effect on lower SF-36 scores (Funk et al. 1997); and a strong influence on facial disfigurement, swallowing and speech scores (Hassanein et al. 2001). Treatment of advanced stage oro-pharynx tumours was significantly associated with worsening of quality of life (Deleyiannis et al. 1997, Hammerlid et al. 1998). In this study, positive neck nodes were associated with worse scores in role functioning (SF-36), social contact, social eating, and senses (EORTC H&N35) after adjustment to other predictors in regression analysis. In contrast, a cross sectional study on a large sample of long-term survivors of head and neck cancer, found no association between the tumour stage and quality of life outcomes in the SF-36 questionnaire (Terrel et al. 2004). A similar finding was reported by Hammerlid and Taft (2001) in a mixed sample of head and neck cancer patients three years after treatment. However, the effect of disease stage on QOL scores was moderated because many patients with stage III & IV cancer who scored poorly at diagnosis died in the first year (Hammerlid et al. 2001b).

(III) Gender: Gender difference in HRQOL outcome is not clear. In the Netherlands, female patients show a trend to have worse scores than male patients one year after treatment (de Graeff et al. 2000), while in the UK male patients tend to report

worse scores than female patients one year after treatment (Rogers et al. 1999d). In this study, male patients reported worse scores in dyspnoea (EORTC-C30), senses and sticky saliva (EORTC H&N35) than female patients; however, the gender factor lost its significance after adjustment for other variables in multiple regression analysis. A Swedish study found that female patients scored worse than male patients at diagnosis and one year postoperatively (Hammerlid et al. 1999a). However, in a subsequent report after three years follow up they found that female patients tend to score better in most of the EORTC-C30 and QLQ-H&N35 scales/items than male patients and female norms patients; they suggested that female patients cope better over time (Hammerlid et al. 2001b, Hammerlid et al. 2001a). Facial disfigurement after surgical treatment of head and neck cancer for patients is common; and high disfigurement scores have been reported in female patients (Hassanein et al. 2001). Also, the role of facial disfigurement in social anxiety (phobia) is strong (Newell et al. 2000). However, the role of facial disfigurement on shaping the social life of head and neck cancer patients is yet to be validated.

(IV) Patients' age: The patient's age was reported to be an important predictor for long term survival (Gleich et al. 2003). A large cross sectional study found older patients had significantly worse scores for physical functioning and role physical (Terrel et al. 2004). In addition, old patients (>65 years) were reported to have worse scores than norms for all the SF-36 scales, while younger patients had similar scores to norms in the Swedish sample, three years after treatment (Hammerlid et al. 2001b). In contrast, the SF-36 scores showed a modest difference for older head and neck cancer patients (65-74) compared to their age-matched norms in the American sample one year after treatment (Funk et al. 1997). Moreover, longitudinal studies on head and neck cancer patients found that age has little influence on HRQOL outcome in the short term or one year after treatment (de Graeff et al. 2000, Derks et al. 2003, Rogers et al.

1999d). In this study, older patients significantly reported worse scores for physical functioning and role physical (SF-36), and senses problems (EORTC H&N35) after adjustment to other variables in multiple regression analysis. The age factor seems to have a weak effect on short term follow-up (one year); however, on long term follow-up the influence of age becomes more evident.

A significant factor in age is that as people grow older they become more fragile and less durable. The findings in Hammerlid et al's (2001) study of larger improvement in EORTC-C30 and SF-36 scores (approaching norms Swedish value) compared to patients aged 65 years or more three years after treatment, demonstrate the ability of younger patients to adapt to changes in the long term (Hammerlid et al. 2001a). Another factor is the increase of medical co-morbidity with age. Surgical patients comorbid with medical problems were more likely to have poorer HRQOL after treatment (Rogers et al. 2000, Terrel et al. 2004).

A study by Hassanein et al (2001) found young head and neck cancer patients reported more functional problems than old patients (Hassanein et al. 2001); however, this finding needs to be validated in a prospective study.

2.5.4 Treatment predictors

Advanced disease requires more aggressive surgical treatment which may result in more disfigurement and functional disability, therefore, patients were expected to score poorly in HRQOL questionnaires (De Boer et al. 1995, Deleyiannis et al. 1997, Rogers et al. 1998a). Treatment predictors considered are amount of bone resection (discontinuity bone resection or not), relation of soft tissue resection to teeth (anterior/lateral or posterior/medial), level of neck dissection (I-III or IV-V) and radiotherapy treatment (yes or no). Multiple regression analysis will consider the predictability of each variable after adjusting for the others.

(I) Radiotherapy treatment: Rogers et al (1999) found patients who received radiotherapy were more likely to score poorly in HRQOL (Pourel et al. 2002, Rogers et al. 1999d, Rogers et al. 2000). De Graeff et al (1999) reported that combined treatment resulted in worse physical symptoms both at 6- and 12-months after treatment (de Graeff et al. 1999, de Graeff et al. 2000). In this study, radiotherapy treatment correlated significantly with low scores for emotional problem (RE) from the SF-36; however, it lost its significance when adjusted for other variables in multiple regression analysis. In the EORTC H&N35, radiotherapy was significantly associated with worse scores for swallowing, speech problems, social eating, sticky saliva, and pain killers; however, multiple regression analysis results showed that radiotherapy was associated only with worse scores for social eating, swallowing, teeth, and sticky saliva. A similar result was reported by Terrel et al (2004) when they found radiotherapy was moderately associated with worse score in social eating, most probably related to reduction in salivary flow (Terrel et al. 2004). Moreover, radiotherapy-related fatigue during and after treatment was reported to have a significant association with survival in head and neck cancer patients three years after treatment (Fang et al 2004). The side effects of radiotherapy are well known and results gathered here collectively demonstrate how the side effects are shaping patients social life. More effort to overcome these side effects will improve patients' quality of life.

(II) Tumour site: Posterior tumours were reported to result in lower UW-QOL cumulative score one year after treatment (Rogers et al. 1999d, Rogers et al. 2000); also, posterior tumours were significant predictors for worse scores in many functional problems even three years after treatment (Hammerlid et al. 2001a). A cross sectional study on H&N cancer patients 6-months to 6-years after treatment reported poor functional scores in posterior tumours (Hassanein et al. 2001). In this study, soft tissue resections medial/posterior to teeth significantly correlated with worse scores for

general health perception (SF-36) and role functioning scores (EORTC-C30); however, this predictor was not significant when other variables were considered in multiple regression analysis. In the EORTC H&N35, posterior/medial to teeth soft tissue resection significantly correlated with worse scores for swallowing, social eating, sticky saliva and coughing. However, after adjustment to other variables in multiple regression analysis, posterior and medial soft tissue resection in relation to teeth associated only with increased problems of sticky saliva. This is not surprising, knowing that posterior/medial tumours are more likely to warrant radiotherapy than anterior/lateral tumours.

(III) Neck dissection: Level of neck dissection considerably influence pain and shoulder function in head and neck cancer patients (Kuntz et al. 1999). In this study, neck dissection level IV-V significantly correlated with worse scores for general health perception and for energy/vitality (SF-36); and social functioning, role functioning global health status, fatigue and feeling ill (EORTC-C30). However, regression analysis showed that positive neck nodes significantly correlated only to worse scores for financial difficulty and social functioning. In the EORTC H&N35, level IV-V neck dissection was significantly associated with worse scores for pain, swallowing, senses, social eating, social contact, teeth, dry mouth, sticky saliva, coughing and nutritional supplement. However, after multiple regression analysis, level IV-V neck dissection was associated with increased problems of dry mouth, coughing, social contact, social eating and swallowing. Terrell et al (2004) reported a mean of 10 points decrease in physical functioning (SF-36) for patients who received neck dissection (Terrel et al. 2004). It is difficult to look at the effect of neck dissection without considering the effect of radiotherapy, as advanced neck node time require more aggressive neck dissection and often adjuvant radiotherapy.

(IV) Bone resection: In the EORTC H&N35, discontinuity bone resection was significantly associated with worse scores for speech problems and opening of the mouth. However, multiple regression analysis demonstrates that discontinuity bone resection was associated with worse scores for pain, social contact, speech, opening mouth, social eating and swallowing. Discontinuity resection of the mandible and with large soft tissue defects was reported to produce the lowest postoperative quality of life scores (Schliephake et al. 1996).

It is noted that the SF-36 domains were significantly correlated with the preoperative predictors only while the EORTC-C30 domains correlated significantly with treatment predictors. The EORTC H&N35 scales/items correlated mainly with the treatment predictors; however, few domains were significantly correlated with preoperative predictors.

2.5.5 Anxiety association with HRQOL

Quality of life domains scores were reported to correlate with future scores and survival, and with domains scores from other questionnaires. High global quality of life at diagnosis in laryngeal cancer patients was strongly associated with high HRQOL after 5 years (Nordgren et al. 2003); and KPS value at diagnosis were moderate predictors for general health and head and neck symptoms one year after treatment (de Graeff et al. 2000). Furthermore, a strong association between the presence of the feeding tube and worst scores in most the SF-36 domains have been reported, and suggest that the feeding tube restricts the patients' diet and social activity (Terrel et al. 2004). De Graeff (2001) found recurrence and survival strongly associated with cognitive functioning scores (de Graeff et al. 2001).

Moreover, a high level of depressive symptoms was a significant predictor of increased severity of general symptoms and poor functioning after treatment.

(Christensen et al. 1999, de Graeff et al. 2000); and HADS-depression values correlated with low performance and advanced stage disease one year after treatment (Hammerlid et al. 1999a). High HADS scores were also strongly correlated with poor functional status and ineffective coping in oral cancer patients (Hassanein et al. 2001).

In this study (section 5.6), anxiety scores from the HADS strongly correlated with scores of HADS-depression, and all the SF-36 scales (except physical functioning), and most of the EORTC-C30 and H&N35 scales/items. A similar association between HADS-anxiety scores and the SF-36 domains scores have been reported in patients with testicular cancer (Fossa et al. 2002).

2.6 Conclusion

In conclusion, oral and pharyngeal cancer patients in this study reported higher anxiety level than previously reported in similar studies from the literature. The HRQOL scores levels were comparable to levels previously reported in similar studies, however lower than UK population norms for the SF-36 questionnaire.

There are few preoperative and treatment received variables significantly correlated with HRQOL domains. Level IV-V neck dissection was significantly associated with worse scores in depression, dry mouth and coughing; also, in conjunction with segmental bone resection they predicted worse scores in social eating, social contact and swallowing (EORTC H&N-35), and social functioning and financial difficulties (SF-36). Radiotherapy treatment was significantly associated with worse scores in swallowing, social eating, teeth problems and sticky saliva. In addition, segmental bone resection separately predicted worse scores for speech, pain, mouth opening. Elderly patients are expected to have worse scores in physical functioning and role limitation due to physical problems and increase in senses problems. However,

young patients especially females are expected to have higher level of anxiety scores. Patients with T_3/T_4 tumours are expected to have more problems with feeding tube.

The EORTC-C30 domains scores correlated with the SF-36 domains scores. However, there was a significant association of anxiety scores with the SF-36 domains scores preoperatively and with the EORTC H&N35 domains postoperatively. This may indicate the value of each questionnaire for time of patients' management (SF-36 at preoperative time and EORTC at postoperative time).

The questionnaires used in this study described effectively the patients' HRQOL and differences between scores at the different stages; however, a limitation for this study was the method and site of assessment. The difficulty with quality of life measurement is that it is stable over time and influenced by several different components. In order to detect small differences between groups, a large sample size is needed (Stromberg A. 2002). The sample size in this study is small so any conclusions are viewed with caution.

To appraise the patients' perception of psychosocial support including level of information about their disease and its effect on quality of life and anxiety a further semi-structured interview study was conducted on a sample of patients and their relatives.

Chapter 3

3. Influence of Psychosocial Support on Patients' HRQOL

3.1. Literature review

3.1.1 Patient education in relation to coping and psychosocial support:

Psychosocial and physiological variables have an important role in the QOL of head and neck cancer population; however, in predicting long-term aspects of QOL the psychosocial variable appears to be more important than physiological variables (Holloway et al. 2005). Head and neck cancer population are at risk of developing disturbances in psycho-social, recreational and sexual functioning, and psychological distress. Worry, anxiety, mood disorders, fatigue, and depression are the main symptoms reported by a considerable number of patients (De Boer et al. 1999). This chapter will review some psychosocial aspects of patients QOL affected by the disease or its treatment.

3.1.1.1 Physical function:

Oral and pharyngeal cancer and its treatment have detrimental consequences on the patient's physical and psychosocial functions. At diagnosis stage, the highest degree of impairment is related to pain symptom; however, during and after treatment functional aspects such as speech, swallowing and movement abilities become more important; and patients evaluate their postoperative QOL on the degree of recovery primarily from functional disorder (Gellrich et al. 2002, Laverick et al. 2004).

3.1.1.2 Disability:

Cancer can result in tremendous financial burdens for the individual, family, and society at large. A large sample of patient from a multi-centre study revealed that more than half of the patients were disabled as a result of their head and neck cancer or

treatment. In this study, neck dissection, chemotherapy, depression, fatigue, and pain were significant predictors for patients being disabled (Taylor et al. 2004b).

3.1.1.3 Nutritional problems:

Studies on head and neck cancer reported that patients are at increased risk of developing severe and sustained nutritional problems especially when receiving radiotherapy treatment. Nutritional problems were summarised in three dimensions: 1) The physical aspect of eating difficulties in the form of reduced ability to chew and swallow as a result of thickened reduced saliva, dryness, swelling, narrowness and pain in the moth and throat. 2) The general bodily tiredness and fatigue from the insufficient nutrition; and loss of will and desire to eat as a consequences of the pain and nausea. 3) The social aspect where patients feels loss of togetherness with family and friends at meal time; this can be due to the self image change (bad breath and difficulty to talk) or taking additional time to complete a meal for using compensatory techniques in chewing and swallowing. The difficulties patients experience in eating may cast a shadow on the success of treatment and can be a source of anxiety for the delay in recovery; this also may add to threat of life for not being able to eat enough (Larsson et al. 2003, Nguyen et al. 2005).

3.1.1.4 Body image:

Diseases affecting body parts of great symbolic significance, such as cancer of the breast, head and neck or ovaries, may damage self-esteem and alter the sense of personal identity (Dropkin 1999). A large cross-sectional survey of patients with disfigurement from different outpatient clinics (including head and neck cancer) was performed by Rumsy et al (2004); in this survey qualitative and quantitative method were used to demonstrate patients concern and satisfaction with care, level of anxiety,

social anxiety, depression, and QOL. The results revealed high psychological distress in this population associated with poorer quality of life; and a strong desire for clinical-based support for appearance-related concerns (such as contact with others, social interaction, exposing the disfigurement to others, ignorance and negative comments by others...etc). Interestingly, authors found that the size of disfigurement was not directly related to the severity of psychological distress; but, positive perception of social support was found to be related to lesser impact of appearance concerns on lifestyle and general perceived worry. This underlines the important role of relatives in the management of social difficulties and in promoting rehabilitation (Rumsey et al. 2004).

A prospective descriptive study by Dropkin (2001) of 75 head and neck cancer patients who underwent surgery found no relationship between facial disfigurement and anxiety. In this study, patients sustained a moderate degree of disfigurement/dysfunction as rated by the investigator; however, anxiety scores measured in the State Trait Anxiety Inventory gradually decreased in the short period after surgery. The author suggests that patient's ability to self care was a better indicator for level of anxiety scores in the short period after surgery (Dropkin 2001).

3.1.2 Psychotherapeutic approaches

The moderate to severe functional and psychosocial difficulties experienced in definitive treatment for oral and pharyngeal cancer patients are associated with anxiety, depression and poor QOL regardless of treatment modalities; and patients evaluate their postoperative QOL on the degree of recovery from functional and psychological disorders. Therefore, in developing psychosocial intervention programs, one must include nutritional assessment, pain control, anti-depressive and/or anxiolytic medications, psychological counselling, early physiotherapy as well as speech rehabilitation (Gellrich et al. 2002, Larsson et al. 2003, Nguyen et al. 2005).

Furthermore, for the significant role of coping as mediating factor between personality and outcome, a coping targeted psychological intervention needs to decrease patient's pessimism and stimulate hopefulness in long-term oral and pharyngeal cancer patients survivors (Holloway et al. 2005, Llewellyn et al. 2005).

The main objectives of psychosocial intervention are to reduce the emotional and physical side effects of the disease or its treatment, to actively monitor and improve patients' coping behaviours and compliance with treatment, to support patients' rehabilitation after treatment and ultimately re-establish higher quality of life (Rehse et al. 2003, Sheard et al. 1999). One of the objectives of rehabilitation is body image reintegration, where patients gradually accept body alteration; learn to compensate for anatomic changes through optimal use of residual structure and function, restoration of self expression, self care and re-socialisation, and anxiety reduction (Dropkin 1999).

A meta-analysis study by Meyer and Mark (1995) reported many forms of psychosocial interventions used in cancer patients with positive effects on emotional adjustment, functional adjustment, and management of symptoms related to the disease and treatment (Meyer et al. 1995). However, there are two major psychotherapeutic approaches adopted by the mental health professional or primary care practitioner:

- Promotion of active coping strategies with the aim of gaining mastery; there are three basic coping styles: problem solving coping, emotion focused coping, and avoidance oriented coping (Endler et al. 2001). A recent program based on a model of understanding the dysfunction associated with disease and its treatment and improving patients' coping skills has been successfully developed and implemented by head and neck cancer nurse specialists. In this program patients learn that not only will they look different but that they will also sound and eat differently; and will learn various strategies to manage these difficulties in the

same way they manage social interaction problems associated with the disfigurement (Clark 2000). Patients' education, including the families, about the medical condition and about steps that can be taken to improve symptoms, or to obtain further assistance may moderate feelings of helplessness, provide peer support and diminish feelings of isolation (Spiegel 1994, Weis 2003).

- Supportive-expressive therapy; the traditional role of the medical practitioner in maintaining a consistent, reliable, caring relationship with patients is often the most important psychotherapeutic factor for patients with chronic or terminal illness. Indeed, once the medical treatment plan is established, the relationship with the physician may be one of the most critical factors in maintaining morale and hope. In both supportive and expressive treatment, the therapists help the patients to understand the illness experience in a meaningful fashion. However, the objectives in supportive treatment are focused more on symptomatic relief and in maintaining psychological equilibrium. This is accomplished by a structured approach, which is more likely to include interventions such as education, reassurance, and advice. This approach is most helpful when based on realistic appreciation of the patient's situation. In the expressive psychotherapy the emphasis is on promoting self-understanding and psychological growth. This treatment, which requires trained psychotherapists, is most suitable for the small minority of medical patients who have identifiable and significant psychological or interpersonal problems, who are ready to understand their feelings, and who have the ability to form a therapeutic relationship (Fawzy 1999, Greer 2002, Weis 2003).

A systematic review of the randomize controlled trials (RCT) for methods of giving information in cancer management showed that attempts to improve communications through different channels can have positive effects on a variety of

patient outcomes. However, the authors found it difficult to comment on the condition under which intervention is most effective, or identify which patients would benefit most from any given intervention (McPherson et al. 2001). Furthermore, the National Comprehensive Cancer Network (NCCN) guidelines for the management of distress provides a summary of which services should be provided in ideal treatment settings, but the NCCN consensus panel did not recommend which forms of psychotherapy/counselling are most appropriate for individual patients (Holland 1999).

A more dynamic approach is the trans-theoretical model (TTM) of health behaviour which has been suggested as a base for selecting psychosocial intervention. According to this model, an individual can be at one of several stages: pre-contemplation, contemplation, preparation, action, and maintenance. An effective intervention, as proposed by TTM, is one that is customised to an individual's stage and moves the individual from one stage to the next (Lauver et al. 2002).

3.1.3 Effect of Psychosocial intervention:

In the literature, the evidence suggesting that cancer patients suffer from a significant long-term psychological distress is on the rise and studies confirmed that psychosocial intervention has a positive impact on QOL in adult cancer patients (Rehse et al. 2003). Dropkin (1999) found that patient's anticipation of disfiguring surgery had a direct relationship with level of anxiety and inverse relationship with effectiveness of patient's coping, postoperative self care, and re-socialisation (Dropkin 1999). Additionally, perceived psychosocial stress in the absence of social supports contributes to both physical and psychological illness (Walker et al. 2003), and considerable evidence in the literature supports the positive influence of various social supports on the psychosocial adjustment for cancer patients (Kugaya et al. 1999, Meyer et al. 1995). The debate now is about whether and to what extent psycho-oncological care can be

effective in moderating the cancer patients suffering. In the following we will look at the effects on two main aspects: prognosis and well being.

3.1.3.1 Effect on prognosis:

A literature review by L. Ross et al (2002) looked at eight studies that assessed the effect of different psychosocial intervention strategies (counselling, group/individual therapy, self-hypnosis, psycho-educational and supportive/cognitive behavioural therapy) on the length of survival of cancer patients. They were no consistent pattern of effect on survival; four studies reported a positive correlation between the intervention and survival from cancer, whereas four studies failed to find this association. None of the four studies which reported positive correlation measured changes in health behaviour, therefore the possible mechanism is unknown (Ross et al. 2002).

3.1.3.2 Effect on well-being:

A review of 43 randomised studies of psychosocial intervention for cancer patients concluded that psychosocial intervention may have a weak effect on well-being and may be most relevant in patients groups who were found on screening to suffer from psychological distress. However, methodological difference between studies (such as the time between diagnosis of cancer and inclusion in the study, patient populations, and intervention strategies and studies design) may have obscured the investigated effects of psychosocial interventions on outcome measures (Ross et al. 2002). Another review of psychosocial interventions used in head and neck cancer patients by Semple C. et al (2004) recognised several distinct categories that have been employed, namely, education, educational support, and psychotherapy. In general studies suggest an overall positive effect on quality of life, though some failed to achieve the desired results (Semple et al. 2004).

Psycho-educational intervention program was effective in reducing anxiety before and after operation especially in patients with high preoperative anxiety sores, and in producing better scores for some of the HRQOL variables measured (Hammerlid et al. 1999b, Sjoling et al. 2003). In contrast, Petruson et al (2002) in a prospective longitudinal controlled study in head and neck cancer patients found that information and emotional support did not improve patient overall HRQOL. They suggested that patients developed a dependent relationship with counsellors which may have helped the patients in the control group to score marginally better QOL. However, authors recommended continuous assessment for the patient's psychological state and if possible customising intervention accordingly (Petruson et al. 2003).

3.1.4 Factors influence the psychosocial support outcome:

The patient's psychological responses, including anxiety, depend on multiple factors such as the characteristics of the medical illness, the individual's personality, emotional conflicts, person vulnerability, and the cultural and social environment of the individuals affected (Dropkin 1999). In head and neck cancer, rehabilitation outcomes are related mainly to the type of treatment and the perception of care; however, there are many other factors (such as coping strategies, patient's gender, and management of eating problems) that can have a positive effect on rehabilitation outcomes (De Boer et al. 1999).

3.1.4.1 Patient age

Age factor has a strong influence on a patient's psychological response. People in different age groups are at risk of different illnesses and health problems. Diseases occurring during young or middle age may provoke concerns about job security, physical attractiveness, and possible rejection by peers. In the elderly, fear of death or

loss of ability to function independently may be more prominent. Moreover, older people tend to seek help less readily than younger patients (Kogan et al. 2000).

3.1.4.2 Personality

Personality may be defined as a person's characteristics that are responsible for relative stable pattern of feeling, thinking and behaviour. Neuroticism is a trait of patient's mental condition, individuals high in neuroticism are assumed to be predisposed to worry, regardless of the presence or absence of threats, and report more subjective health complaints than stable individuals. Extroverted people, on the other hand, are considered to be sociable, active and talkative and enjoy change and excitement in their lives; and found to associate with a subjective well being.

There is limited data regarding the role of personality trait on reported HRQOL. A review article by Llewellyn C.D. et al (2005) reported a few studies that indicate a direct relationship between patient's optimism score and their HRQOL rating. In contrast, patients scoring highly for neuroticism were more likely to have a low HRQOL (Llewellyn et al. 2005). Another study by Yu C. et al (2003) looked at the role of optimism on QOL in a convenient sample of nasopharyngeal cancer patients referred for radiotherapy treatment. In this study patients completed the questionnaire at 1-months and 5-months post-radiotherapy treatment; optimism and eating ability were measured by two 11-point (visual analogue line scored from 0-10) self rated items; QOL measured by the Functional Assessment of Cancer Therapy (FACT-G). They found eating ability at 1-month was significantly predicted optimism at 5-months; and optimism and QOL were significantly correlated at 5-months. They suggested that optimism did mediate the impact of eating ability on the overall quality of life at 5 months post-radiotherapy (Yu et al. 2003). Also, another study by Holloway R. et al

(2005) found patient's pre-morbid pessimism to be a valid predictor of all QOL measures in long term head and neck survivors (Holloway et al. 2005).

A study by Aarstad H. et al (2003) on head and neck cancer patients found that higher neuroticism scores were significantly associated with lower functional QOL scores one year or more postoperatively, but not at diagnosis. This association was independent of age, gender, level of education, the number of persons in the household and smoking history. Also, there was an indication for positive association between extroversion scores and the general health/QOL symptom scores (Aarstad et al. 2003).

The significant role of coping strategies as well as locus of control in shaping rehabilitation outcome was highlighted also in a review paper by De Boer at al (1999). Patients with internal locus of control have more self-confidence and greater feeling of self esteem, and there was a decrease in symptoms of distress in patients used either approach or avoidance coping strategies (De Boer et al. 1999).

3.1.4.3 Social Support:

Social deprivation indicates that individuals lack access to employment, education, and family and social activities; therefore, denies patients access to coping resources. Generally, high social class is correlated with increased life expectancy, and a low social class is correlated with increased vulnerability to illness and early death (social class is expressed in terms of occupational ranks, income, and education). Lower class people are slower to seek treatment than their upper class counterparts are. Also, mental illnesses are strongly associated with social class, with the highest rate of mental illness consistently being found among the lowest social classes (Goldman 2000).

A study by Woolley et al (2005) on a number of oral and pharyngeal cancer patients found a clear indication that young unmarried patients who smoke and drank alcohol heavily were more likely to live in a deprived area; and their QOL seem to deteriorate quickly. They also found that deprivation was linked to more advanced disease at presentation. However, it was interesting that during follow-ups, patients living in the least deprived areas reported good HRQOL; and authors suggested that the present of intact social network (friends, family, and work) provided the resources for coping (Woolley et al. 2005).

Social support was suggested to have a positive influence on the rehabilitation results (De Boer et al. 1999). However, a review article by Llewellyn et al C.D. (2005) found social support to be a complex interactive construct, which may only be effective when matched with the patients need (Llewellyn et al. 2005). The social support may have a buffering effect on the psychosocial impact of disfigurement on well-being as reported in a sample of female head and neck cancer patients (Katz et al. 2003).

Social support can also be related to patient's education level; as education is a significant predictor for the individual socioeconomic status. A cross sectional survey of a large sample of cancer patients who received radiotherapy treatment demonstrated that patients with good socioeconomic status were highly educated and had the best overall survival and local control. The better outcome in highly educated patients may be attributed to many factors such as better understanding of the importance of receiving the treatment as prescribed or better support at home which improve tolerance of treatment, or better communication with doctors which led to reporting early signs of the disease (Konski et al. 2003).

Furthermore, a significant role of social support was indirectly backed-up by a finding in a large survey of cancer patients investigating patient's awareness and use of

cancer support and information resources. The study revealed that the use rate was quite low; and one of the most commonly reported barrier to using such services was the presence of adequate psychosocial support (Eakin et al. 2001).

3.1.4.4 Satisfaction with information and consultation

Information support is one of the factors that clearly have a positive influence on the rehabilitation results (De Boer et al. 1999). One prospective study on nasopharyngeal cancer patients going for radiotherapy suggested that patients reporting more satisfaction with the information provided approximately 1 month after the end of radiotherapy, had a better QOL 4 moths later (Yu et al. 2001).

Affective patient's interaction during the consultation can improve patient satisfaction and consequently their quality of life. Research showed that multidisciplinary team (MDT) attention to the psychosocial concerns of cancer patients when providing medical treatment predicted patient satisfaction with medical care (Walker et al. 2003). This significant role for the MDT has been recognised in the recent Improved Outcome Guidance (IOG) for head and neck cancer published in November 2004 (Bradley 2005). A large survey of cancer patients and their clinicians demonstrated that both patients and clinicians were very satisfied in their consultations; however, patients with high psychological distress scores were less satisfied than patients with lower scores. Also, an important mediating factor which emerged in this study is the patients waiting time before the consultation, where patients perception of having to wait too long in clinic before seeing a doctor affected their satisfaction with treatment (Shilling et al. 2003).

Involving patient in the consultation, exploring the patient's ideas and concerns, and assessing and responding to the patient's understanding have been described as elements of "patients-centred" communication. In this method of communication the

discussion agenda evolves and changes according to the patient's need and stage of treatment. Research showed that patients-centred communication is associated with increased patient satisfaction with information; and there are indications that mental health is associated with satisfaction with information. Therefore, interventions to increase patient-centred behaviours among physicians are one possible method for improving patient satisfaction with information (Mallinger et al. 2005).

A large survey of sources of information in cancer patients revealed that the hospital consultant, general practitioner, chemotherapy/radiotherapy staff, ward staff and family/friends were the most frequently cited sources. The source that scored highest in term of quality of information was the specialist/Macmillan nurse; while GPs and media sources scored poorly in term of quality of information. The study identified two important area that can have implication in practice; the presence of a member of the primary health care team with the necessary knowledge to meet the information needs of their cancer patients, and family/friends as a crucial source of information for many patients (Mills et al. 2002).

3.1.4.5 Behavioural factors associated with HRQOL:

Excess alcohol intake and smoking was associated with worse HRQOL in head and neck cancer population (De Boer et al. 1999, Llewellyn et al. 2005). However, head and neck cancers are no longer exclusively associated with alcohol and smoking, and people living in deprived areas are more likely to get cancer in the head and neck and more likely to die of their cancer than people living in affluent areas (Bradley 2005).

3.1.4.6 Depressive symptoms

Depression was significantly related to but did not predict HRQOL. It is difficult to say for sure which one has the overriding influence on the other as patients with time go through adaptive and adjustment processes as well as the role of mediating factors such as coping and support networks (Llewellyn et al. 2005). Supporting this is the findings of high level of adjustment and positive well being in head and neck cancer patients with low level of depression (Katz et al. 2003).

3.1.4.7 The patient-carer psychological relationship

Partners, family members and friends play a pivotal role in providing home care to cancer patients. However; working with cancer patients is always demanding and it is not unusual for caregivers to experience stress, exhaustion, and anticipatory grief. These feelings encourage them to adjust to their new circumstances and learn new skills to be able to provide the guidance and support patient need. Nurses have a very important role in facilitating caregivers in the caring process, working in partnership with caregivers, affirming their valuable contribution, assisting them with their work and supporting them in finding a positive meaning in their experience (Mok et al. 2003).

A study of the relationship between the patients HRQOL and carer psychological status at two palliative care centres in the UK demonstrated that carer anxiety and burden was associated with greater patient distress and pain (Harding et al. 2003). Also, a cross sectional study by Vickery et al (2003) assessed the impact of head and neck cancer (HNC) and facial disfigurement on the QOL of patients (surgically and non-surgically treated) and their partners. The study found that surgically treated patients and their partners reported higher level of anxiety compared to non-surgically treated patients and their partners (Vickery et al. 2003).

Assessment of the impact of head and neck cancer on the quality of life of patient's partner is difficult and few studies reported a refusal of significant number of eligible individuals who may still experience significant difficulty in adjusting to their circumstances (Harding et al. 2003, Vickery et al. 2003). Therefore, studies are likely to underreport the burden of cancer on partners.

3.2. Aims and Objectives:

The study aims to:

- Describe or understand patient's attitude and behaviour about services provided, and explain its successes and shortcomings.
- Formulate recommendations that can improve applied services.
- Interpret the quantitative data collected in other quality of life questionnaires.

3.3. Materials and Methods:

3.3.1 Ethical approval

Approval for the study was sought and gained from the Ethical Committee of the University College London to which the clinic and hospital belonged and where the interview will be conducted. The informants were assured that their responses would be confidential, and their participation in the study is on voluntary bases. Also, informants were free to withdraw from the study at any time without giving any reason and that this will not affect their treatment by any mean.

3.3.2 Study design and implementation

This is a qualitative in-depth semi-structured open-ended interview study involving a mix of a selected pre and postoperative head and neck cancer patients. In this method participants are allowed to freely express their ideas and information. The researcher, on the other hand, frame questions spontaneously, probe for information and take notes. The aims of the study are listed below; however, the nature of problems negotiated in these aims is difficult to materialise with a high degree of accuracy and validity; also, there was a short time frame allocated for the study with some resources restrains. Therefore it was appropriate to use this method of research.

The advantages of this method are:

- Information is provided directly from knowledgeable people.
- It provides flexibility to explore new ideas and issues not anticipated during planning.
- It is inexpensive and simple to conduct; it typically has a smaller sample size and narrower focus, and often requires less technical and statistical expertise.

- It is good at providing in-depth understanding of complex psychosocial issue or processes.

The disadvantages are:

- It is not appropriate if quantitative data are needed (i.e. not suitable for producing generalise-able data).

- It may be biased if informants are not representative of the population studied (results are almost always based on non-representative sample). Therefore, the commonness of the findings is not presented.

- It is susceptible to interviewer biases.

- It follow no established procedure and relies on common senses and experience, therefore it may be difficult to prove validity of findings.

The Interviews were conducted according to the following steps:

Step1. Formulating the study questionnaires: The specific concerns of the study were the adequacy of informational and psychosocial support provided to patient and how it may be improved. Also, we wished for more interpretation of findings in the quantitative HRQOL data.

Step2. Preparation of the short interview guide: The focus of the study was on 8 major domains; doctors support, team support (other than doctors), social support, patient coping attitude, body image, nutritional support, disability, and physical ability (table 3.4.1). Assuming this will cover the subject of concern more thoroughly. Each topic will be negotiated in more than one question for more validity of the data. An example is doctors' support, this topic is covered in questions about patient confidence in doctors, how clear and honest was the information, sensitivity of the doctors during

communication, was patient given choices in treatment, was the patients aware of treatment side effects, and was the appointment time sufficient to discuss information provided by doctors. One may notice that some of the questions in the interview were addressed in the questionnaire used in the 1st study in chapter 1; however, it is only because the issues are significant to psychosocial support process and during the interview the subjects were discussed more thoroughly.

The guiding questionnaire formulated has a Likert scale for each question and a space for notes to be completed by the researcher for this purpose (see appendix XIII). The questions wording was elicited from qualitative questionnaires reported in the literature for measuring patient's information and psychosocial needs. The questions were piloted in few interviews and modified accordingly. Thereafter, the questions were reordered after omitting some questions; this is to insure a good flow of questions as this will keep the patient more focused, and avoiding repetition of subjects as well as removing unrelated questions.

Table 3.4.1 Contents of the semi-structures interview questionnaire

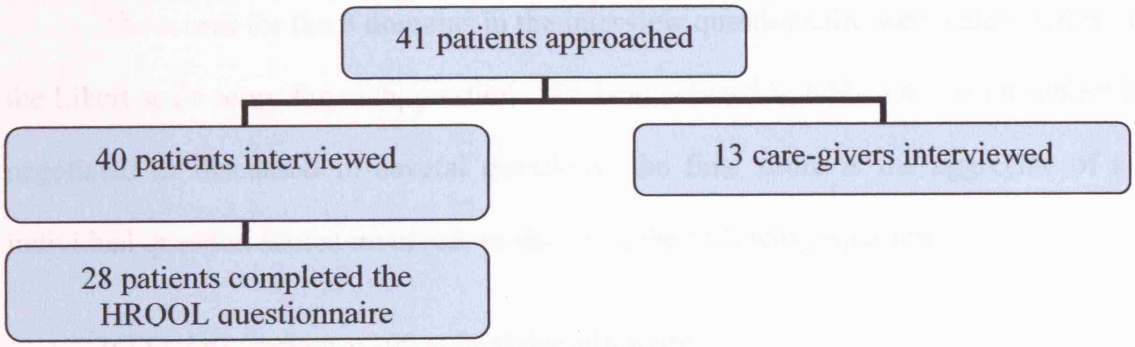
Domain examined	**Questions related**
Doctors support	q1,q2,q3,q4,q5,q6
Hospital support	q7,q8,q9,q10,q11,q12,q13,q14,q15,q20
Social support	q12,q16,q18,q19,q22
Coping attitude	q1,q14,q21,q23
Body image	q13,q14,q16
Nutritional support	q10,q16,q17
Functioning & Disability	q14,q17,q20

Step3. Selecting key informants: In qualitative research, the purpose of sampling is to maximise information, not facilitate generalisation (Larsson et al. 2003, Nguyen et al. 2005). Therefore, we aimed to have a representation of patients from different stages of treatment. Thus, the patient sample in this study contained a mixture of oral and pharyngeal cancer patients attending the unit for consultation or review or in the hospital. We planed to have 30 patients with complete set of HRQOL questionnaires used in the previous chapter (Chapter 2) and an interview form. The patient's criteria were to be competent in speaking and understanding English and aged at least 16 years. The standard applied and services provided in the unit were described previously (Chapter1).

Step4. The interview: Patients were identified by the nurses in the unit/ward or by the researcher during their regular visit to the clinic or the hospital. 41 patients were approached, one patient refused to be interviewed after waiting for long time in the clinic. The interviews were carried out in a quiet room where the patients were introduced briefly to the study and received a written information sheet, patients were invited to participate and sign a consent form if they wished to be interviewed with the knowledge that there is no obligation to participate and can pull out any time from the study without any effected on treatment provided. The interview were carried out after the consultation and lasted on average for 40-60 minute. It started by establishing rapport with patients, establishing some facts about stage of treatment and/or treatment received. Questions always started with present then moved to questions about the past or future sometimes. Patients were asked to give a rating from 0-3 for the service enquired about in the question during the conversation. Yes and no answers were investigated furthermore to encourage patient to express their opinions when possible. The interviewer maintained sympathetic neutral attitude and patients were encouraged to speak freely guided by the interviewer question, however, controlled (time wise) as

much as possible. At the end patients were provided thereafter with a stamped addressed envelop that contain the HRQOL questionnaires to complete and send back. Only 28 patients returned the HRQOL questionnaires.

Only 13 carers agreed to participate and were interviewed. It was difficult to interview carers at the same time due to: lake of time, when it was inappropriate to separate the patient at that time (after a few attempts), or when patients were alone in the clinic. Therefore, carers were interviewed via the phone later at home with the help of one of the nurses. However, this also proved to be difficult for many reasons such as carer being busy at that time or not answering the phone (possible wrong phone number) or they prefer not to talk about it.



The graph illustrates the number of patients and carer recruited in the study.

Step5. Taking notes: The interview notes were made during and at the end of each interview spontaneously for accuracy. Later, information were organised and summarised under the main eight categories listed.

3.3.3 Scoring and Statistical analysis

The interview summary sheets (the questionnaire and the interviewer notes) were gathered with the patient's HRQOL questionnaires data, patient's demographics, and patient's disease/treatment data taken from the department's computers or hospital case notes. The combined data was tabulated using the SPSS-(Statistical Programme

for Social Science) version 11; the interviewer notes were further recoded and together with patients' recommendation were organised and summarised under the 8 major subjects.

Descriptions of the participants involved in the study are summarized in tables by using percentages, means, standard deviation, confidence intervals (95%) and box & whisker plots (25^{th} and 75^{th} centiles and range) where appropriate. Correlations are tested by the Pearson Chi square test for correlation and scatter plots where appropriate. As this is a qualitative study the focus will be on generating information; therefore, there will be less emphasis on statistical significance. HRQOL missing data will be handled as described earlier in chapter 2.

The scores for the 8 domains in the interview questionnaire were calculated from the Likert scale score for each question. As demonstrated in table 3.4.1, each subject is negotiated or discussed in several questions; the final score is the aggregate of all individual question scores involved, as shown in the following equation:

$$((\sum Q_n / n) / \text{range}) \times 100 = \text{final domain score}$$

Where: $\sum Q_n$ = the aggregation of the questions score related to the domain

n = number of questions related and answered

Range = range of the scale for the question (i.e. 0-3)

Example: social support final score = (((q12+q16+q18+q19+q22) / 5) / 3)) x 100

Missing answers in each domain are accounted for in the equation by dividing the result from aggregating the questions scores by the number of questions answered.

3.4. Results:

3.4.1 Patients' characteristics:

There were 40 patients interviewed in this study with age range from 26 years to 85 years and a mean of 60 years (SD 12 years) (figure 3.4.1). A summary of the patients' demographic and disease characteristics are presented in tables' 3.4.2 and 3.4.3. There are only 28 patients completed the HADS and the HRQOL questionnaires and those are going to be considered separately when looking at correlations between patients' scores for the 7 psychosocial domains rated at the interview and their HADS/HRQOL scores. However, for correlations between patient patients' scores for the 7 psychosocial domains rated at the interview and their characteristics, all the 40 patients will be included.

There is a many missing data in some variables in the summary tables, this is due to that recurrent tumours (9 patients) usually are not staged by the TNM classification, and there are connective tissues cancers in bone; and some are not found in the patient case note. Also in the demographics, some data were to be colleted from the patients directly like smoking and living with a partner but were missed at the beginning of the research.

Figure 3.4.1: Patient age range

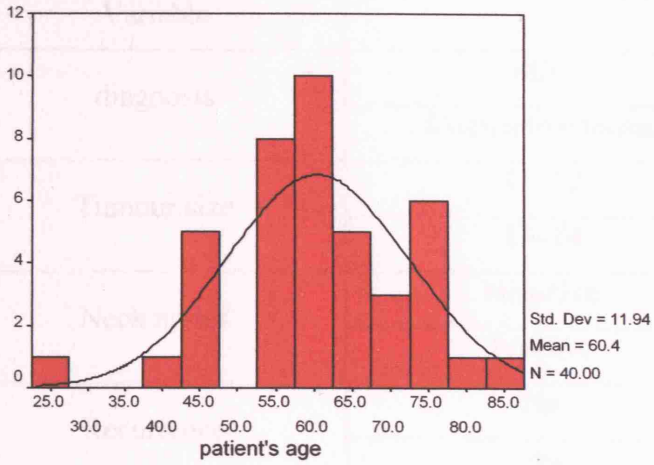


Table 3.4.2 Patients characteristics

variable		frequency	missing
Gender	Female	14	
	male	26	
Marital status	Single/widow	16	2
	Married/couple	22	
House partner	Alone	9	12
	Family	19	
Education level	Primary school	7	1
	Secondary school	8	
	High school	7	
	College / University	17	
Employment status	Employed	14	
	Not employed	26	
Income level	Below average	10	1
	Average	19	
	Above average	10	
Smoking	No	32	
	Yes	8	
Alcohol	No	30	1
	yes	9	

Table 3.4.3 Patients' disease and treatment characteristics

Variable		Frequency	missing
diagnosis	SCC	38	
	Connective tissue	2	
Tumour size	T1-T2	17	11
	T3-T4	10	
Neck nodes	Negative	15	11
	Positive	12	
Recurrence	No	29	
	yes	9	
Stage of treatment	Preoperative	2	
	0-3 months	11	
	3-12 months	13	
	> 12 months	14	
Bone resection	No or rim resection	32	
	Segmental resection	6	
Soft tissue removed in surgery	Anterior / lateral	8	3
	Posterior / medial	27	
Neck dissection	I-III	7	9
	IV-V	22	
Reconstruction	Non-vascular	11	3
	Vascular	24	
Radiotherapy	No	15	1
	Yes	22	

3.4.2 HAD scores:

The HAD scores are presented in two ways, one dichotomised around 7 for caseness of anxiety or depression, and by using the raw scores also for correlations at later stage.

Table 3.4.4: Summary of patients HADS scores (dichotomised around 7)

	Frequency	
	Score <8	7< Score
Anxiety	19	9
Depression	25	3

Table 3.4.5: Summary of patients HADS score (raw score)

	Median	Mean
Anxiety	5	5
Depression	4	4

Figure 3.4.2: Summary of patients HADS scores

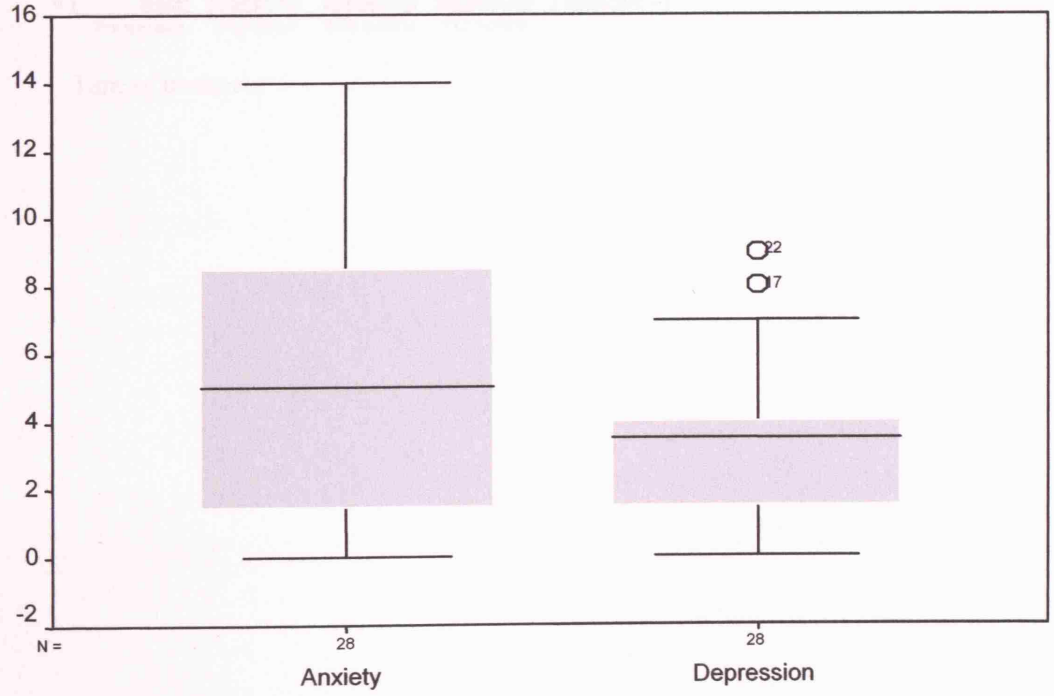


Figure 3.4.3: Anxiety and Depression scores at different times

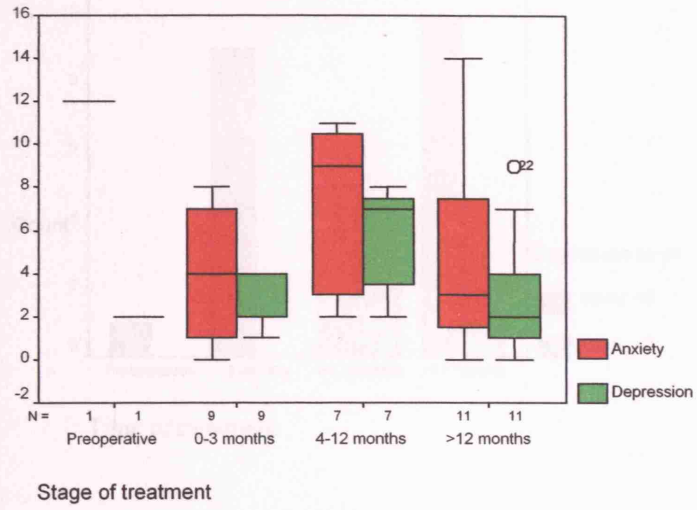


Figure 3.4.4: distribution of patients with Anxiety at different times

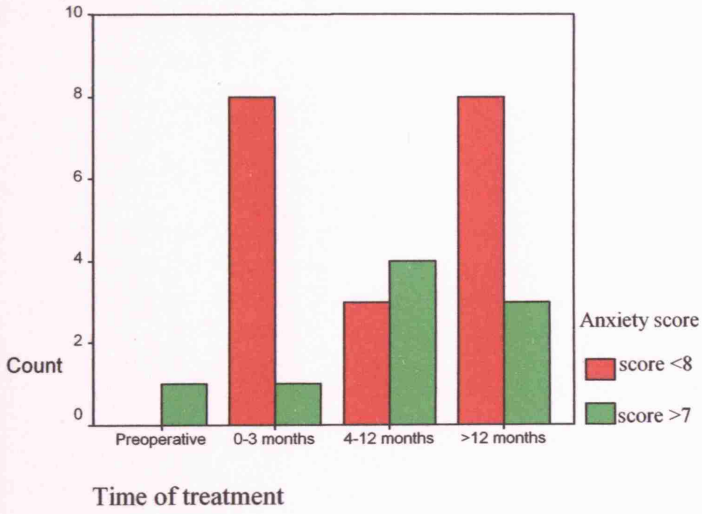
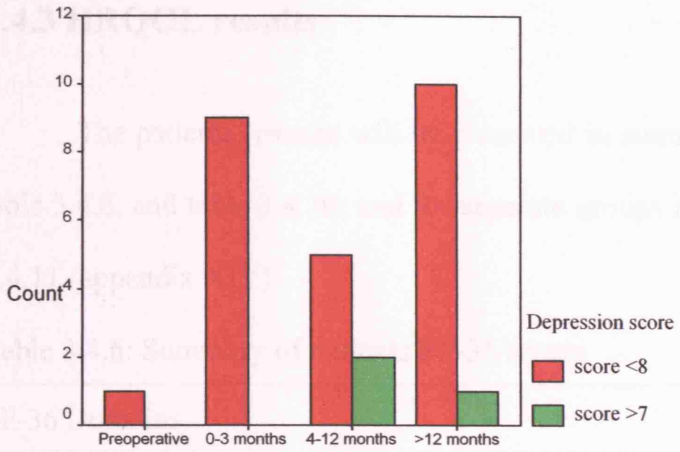


Figure 3.4.5: distribution of patients with depression at different times



Time of treatment

3.4.3 HRQOL results

The patients' results will be presented in summary of all patients in table 3.4.6, table 3.4.8, and table 3.4.10; and for separate groups in table 3.4.7, table 3.4.9 and table 3.4.11 (appendix XIV).

Table 3.4.6: Summary of patients SF-36 scores

SF-36 Domains	Median	Mean
Physical function	70	67
Role limitation due to physical problems	0	42
Role limitation due to emotional problems	100	59
Social function	67	68
Mental health	64	71
Energy/Vitality	55	59
Pain	67	68
General health perception	45	49

Figure 3.4.6: Patients' SF-36 summary scores

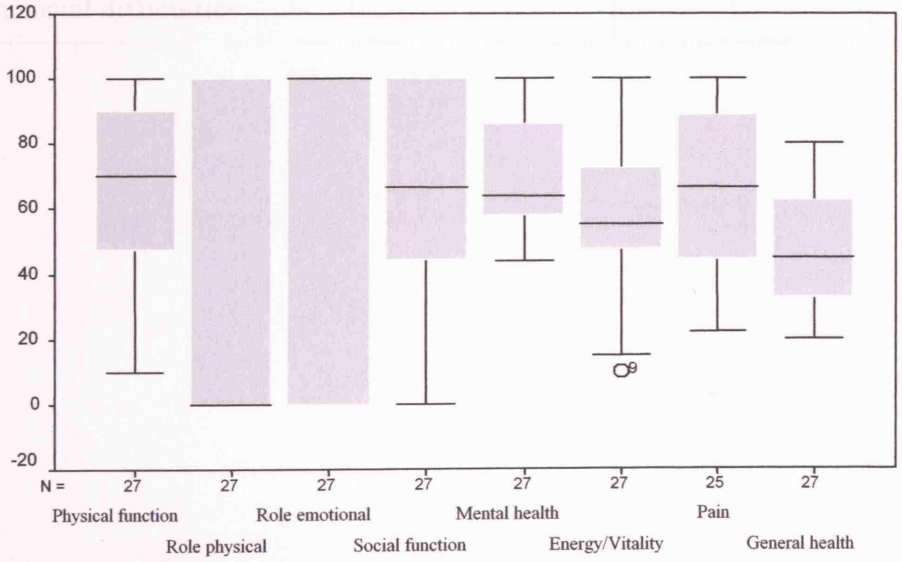


Table 3.4.8: Summary of patients EORTC-C30 scores

EORTC-C30 Domains	Median	Mean
Global health status	67	64
Physical functioning	83	78
Role functioning	67	68
Emotional functioning	75	76
Cognitive functioning	83	84
Social functioning	67	69
Fatigue	33	36
Nausea & vomiting	0	14
Pain	17	28
Dyspnoea	0	12
Insomnia	33	39
Appetite loss	33	36
Constipation	0	15
Diarrhoea	0	19
Financial difficulties	17	24

Figure 4.7: Patients EORTC-C30 Summary scores

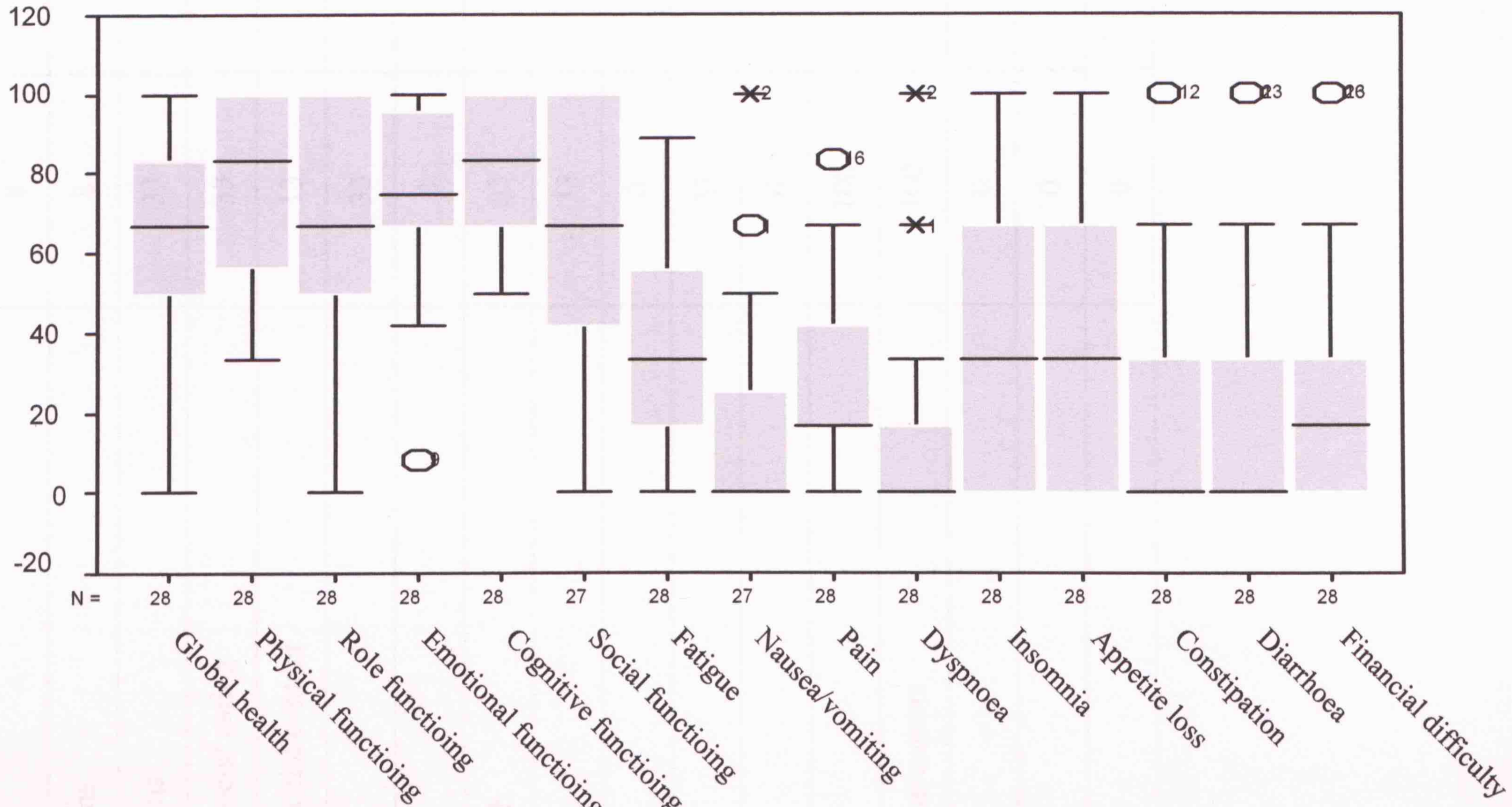
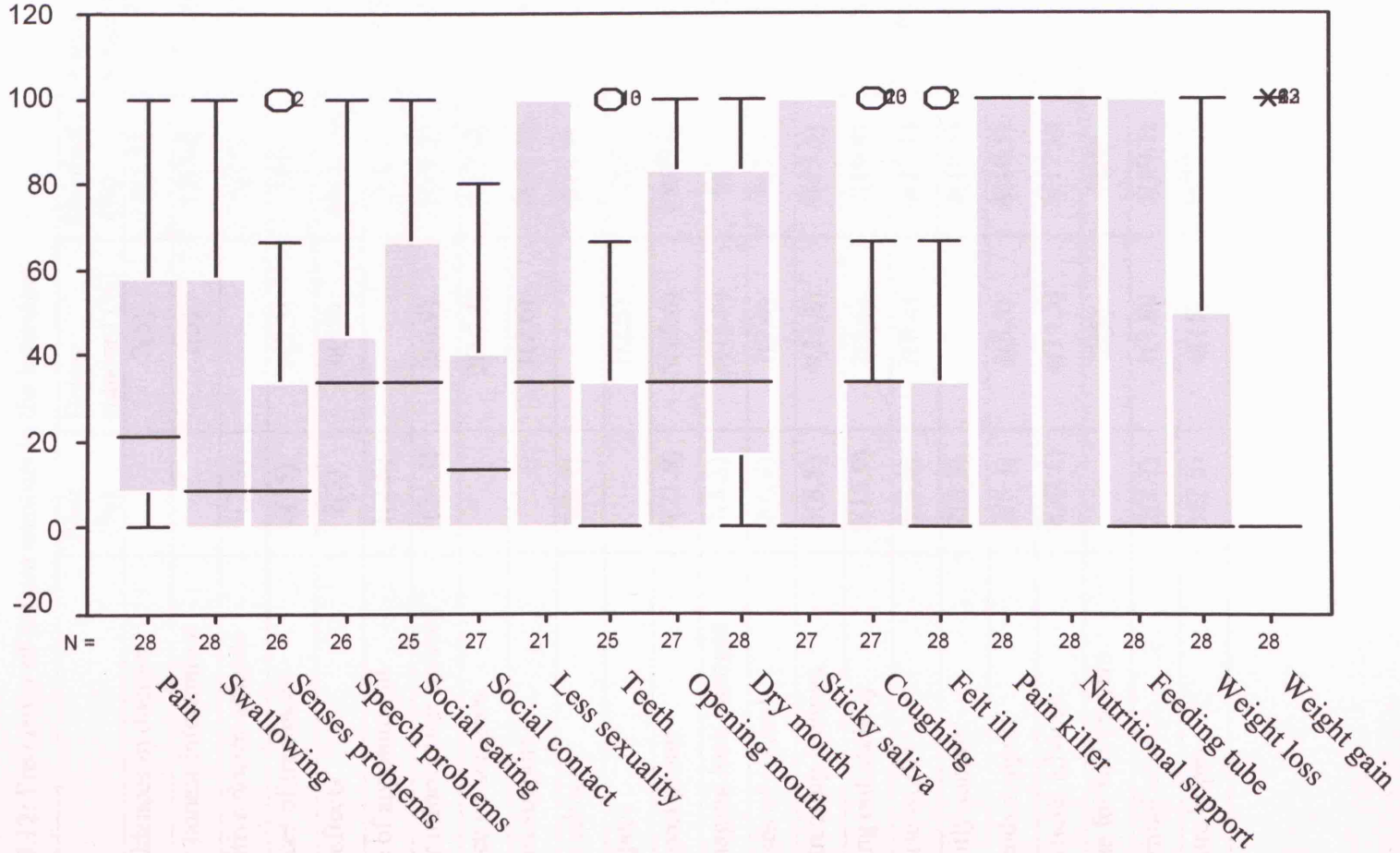


Table 3.4.10: Summary of patients EORTC-H&N35 scores

EORTC-H&N35 Domains	Median	Mean
Pain	21	32
Swallowing	8	29
Senses problems	8	21
Speech problems	33	33
Trouble with social eating	33	38
Trouble with social contact	13	20
Less sexuality	33	44
Teeth	0	27
Opening mouth	33	43
Dry mouth	33	46
Sticky saliva	0	40
Coughing	33	30
Felt ill	0	15
Pain killers	100	64
Nutritional supplements	100	54
Feeding tube	0	32
Weight loss	0	25
Weight gain	0	11

Figure 4.8: Patients EORTC-H&N35 summary scores

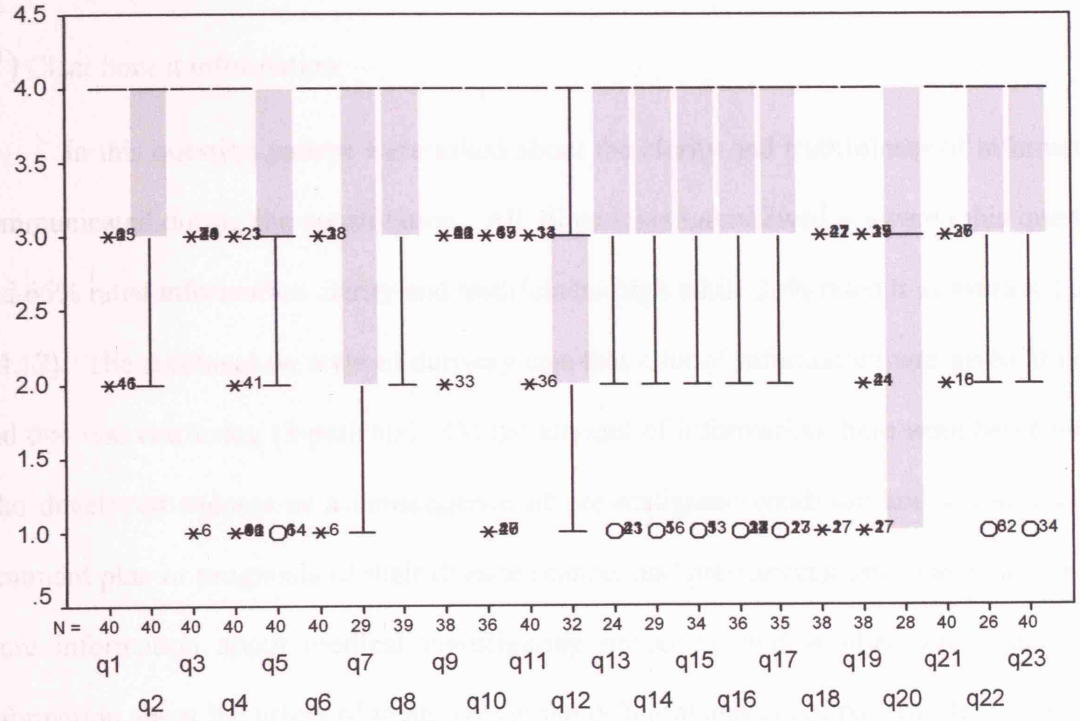


3.4.4 Patient interview results

Table 3.4.12: Frequency of patient answers in the interview

	Poor (%)	Below standard (%)	Standard (%)	Above standard (%)
q1. Confidences in doctors		2(5)	3(7.5)	35(87)
q2. Clear honest information		2(5)	12(30)	26(65)
q3. Sensitive doctor attitude	1(2.5)		6(15)	33(82.5)
q4. Choices of treatment	6(15)	1(2.5)	2(5)	31(77.5)
q5. Side effects	2(5)	6(15)	13(32.5)	19(47.5)
q6. Time of appointment	1(2.5)		3(7.5)	36(90)
q7. Other information sources	7(24.1)	2(6.9)	5(17.2)	15(51.7)
q8. Advice on services		2(10.3)	7(17.9)	28(71.8)
q9. Nurses support		1(2.6)	7(18.4)	30(78.9)
q10. Diet advices	3(8.3)		5(13.9)	28(77.8)
q11. Respect		1(2.5)	2(5)	37(92.5)
q12. Support group	7(21.9)	5(15.6)	13(40.6)	7(21.9)
q13. managing look changes	2(8.3)	3(12.5)	6(25)	13(54.2)
q14. Senses of control	2(6.9)	1(3.4)	9(31)	17(58.6)
q15. Distressing feelings	3(8.8)	4(11.8)	8(23.5)	19(55.9)
q16. Going out socially	5(13.9)	2(5.6)	7(19.4)	22(61.1)
q17. House work	3(8.6)	3(8.6)	6(17.1)	23(65.7)
q18. Family support	2(5.3)		4(10.5)	32(84.2)
q19. Friends support	2(5.3)	2(5.3)	4(10.5)	30(78.9)
q20. Financial advices	9(32.1)	4(14.3)	5(17.9)	10(35.7)
q21. Time for self/prayers		2(5)	4(10)	34(85)
q22. Spiritual advisor	2(7.7)	1(3.8)	5(19.2)	18(69.2)
q23. Future hopes	1(2.5)	6(15)	9(22.5)	24(60)

Figure 3.4.12 : Patients interview summary scores



(1) Confidence in the doctor

The question asks patients about their confidence in their doctors (mainly the consultants); all 40 patients answered this question, and 87% of them have high confidence in doctors (table 3.4.12). Some patients feel that without this confidence in doctors they will not come back to this hospital (5-patients). Also, one patient found that the use of new technology in treatment of cancer (such as PDT) is important factor for the strong confidence in doctors. Nevertheless, one preoperative patient was less confident in doctors for the delay in diagnosis of Osteo-sarcoma after several local resections.

There is a trend for increased patients confidence in doctors with lower level of patients education (r_s = -0.3; n = 39; p = 0.06. r^2 = 0.09). Also, patients with vascular flaps

tend to have more confidence in their doctors ($\chi^2(2) = 7.2$; $p = 0.028$). There was a trend for patients with high confidence in doctors to have less anxiety ($r_s = -0.34$; $n = 27$; $p = .08$. $r^2 = 0.116$).

(2) Clear honest information

In this question patient were asked about the clarity and truthfulness of information communicated during the consultation. All 40 patients interviewed answered this question and 65% rated information clarity and truthfulness high while 30% rated it as average (table 3.4.12). The comment on style of delivery was that a lot of information was given at once, and that was confusing (3-patients). On the amount of information there were two patients who developed cancers as a consequence of pre-malignant condition and not sure about treatment plan or prognosis of their disease (cancer and pre-cancer); also one patient wants more information about medical investigating procedure and another one wants more information about the effect of treatment on the different aspects of patient life. There was one patient who would have liked a name of someone he could call once he had digested information (usually at home) and may have some questions.

(3) Sensitive doctors attitude

This question asks patients about how sensitive doctors were when communicating information with them. All 40 patients answered this question and the majority rated doctors high for being sensitive (table 3.4.12). The main comment on this issue is that a lot of information was given at once, and that was overwhelming (3-patients). The other comment was about breaking bad news; two patients said the biopsy results was delivered bluntly, and one patient was not introduced to the people in the room in the MDT clinic when received the biopsy results. Also, one patient criticized the doctors for not assessing patient's education level (patient was illiterate) and communication at the period directly

after operation was a major problem could have been avoided. There was a weak trend for female patients to be less satisfied with doctor sensitivity ($\chi^2(2) = 5.37$; $p = 0.07$).

(4) Choice of treatment

This question asks patients about treatment choices provided for their disease; majority of the patients (77.5%) felt comfortable about options provided (table 3.4.12). There were 4 patients who felt that they have discussed the treatment plan offered thoroughly and made there decision; however, 8 patients believed they had not been offered alternative treatments and took what was offered. Another 10 patients decided to trust the doctors for what best for them; the reason for that put forward by some patient is that they doubted their ability to take the correct decision and not much time to think (3-patients).

There was a positive correlation between patients rating for being comfortable with choices of treatment provided and the time after treatment, the longer the time the more comfortable the patient ($r_s = 0.44$; $n = 40$; $p = 0.005$. $r^2 = 0.194$). Also, there was a trend for patients being more comfortable with treatment choices provided with pain scores; the more comfortable the patients with choices provides the better the pain symptoms in the SF-36 ($r = 0.4$; $n = 25$; $p = 0.049$. $r^2 = 0.16$) or in the EORTC-C30 ($r = -0.42$; $n = 27$; $p = 0.031$. $r^2 = 0.176$).

(5) Side effects

This question asks patients about how well informed about treatment side effects; all 40 patients answered this question and less than half of the patients (47%) were very happy for what they have been told (table 3.4.12). The rest of the patients have some reservation about what they have been told or what they found after surgery. Their main comment was that they had the information but not realizing the magnitude of treatment side effects until experience it or postoperatively, much more than imagined. Also, patients

concern was about the long term side effects as well as the immediate ones (11-patients). Another group of patient said they were not fully aware of the treatment consequences/side effects, told about serious ones only (8-patients). There were two patients who found side effects are shocking, distressing and confusing when it happens even when patient knows about it. Some other patients were more relaxed about the issue of treatment side effects as one patient said he deals with complications when it happens, day to day; and another one did not want a lot of information.

In this question their was a trend for female patients to be less satisfied about side effects information provided ($\chi^2(3) = 8.26$; $p = 0.04$); and a stronger association between recurrence and satisfaction about information, where people with recurrence being more satisfied with information about side effects ($\chi^2(6) = 19.85$; $p = 0.003$). Patients satisfied with information on side effects tend to have less problems with teeth ($r = -0.4$; $n = 25$; $p = 0.049$. $r^2 = 0.16$).

(6) Time of the appointment

This question asks patients about what they think about their appointment time; all 40 patients answered this question and the majority (90%) is very satisfied the way it is going (table 3.4.12). The only comment was the long waiting time in the clinic, setting in a small inconvenient space, for only 5-min meeting (7-patients).

There was a strong trend for female to be less satisfied with length of their waiting time during their appointment ($\chi^2(2) = 8.25$; $p = 0.016$), and for patients with higher income to be less satisfied about the length of waiting time in the clinic for their appointment ($r = -0.36$; $n = 39$; $p = 0.026$. $r^2 = 0.13$).

(7) Other information sources

This question asks patients sources of information other than the consultant. Not all patients answered this question as some find it not applicable; only 29 patients answered it and half of them (51.7%) were satisfied with the information source they have (table 3.4.12). Majority of the patients said that they had received only verbal information from the doctors; 9 of them said other information sources are not needed. Another 6 patients said information from sources other than doctors may be confusing and could complicate things; and two patients find it inappropriate to give leaflets for serious disease like cancer (serious, frightening, complicated information in easy, reassuring manner). There were 6 patients who were provided with information leaflets from nursing staff, and one patient said leaflets are available at the rack in the clinic. Nevertheless there were 6 patients who were not satisfied with level of information and they looked for more on the internet, from friends, other doctors, and magazines; and wish there was some direction for internet sources. One patient was of concern as none of the staff know she was illiterate; therefore, available source for additional information was not suitable.

There was a trend for female patients to have lower rating for sources of information other than the consultant ($\chi^2(3) = 7.7$; $p = 0.05$). Also, patient rating for other sources of information was positively associated with lower level of limitation due to emotional problems ($r = 0.52$; $n = 18$; $p = 0.03$. $r^2 = 0.27$) and higher energy and vitality ($r = 0.6$; $n = 18$; $p = 0.009$. $r^2 = 0.36$) in the SF-36 questionnaire; also negatively associated with more speech problems ($r = -0.48$; $n = 19$; $p = 0.036$. $r^2 = 0.23$) and troubles with social contact ($r = -0.6$; $n = 18$; $p = 0.017$. $r^2 = 0.36$) in the EORTC-H&N35 questionnaire.

(8) Advice on services

This question asks patients about their knowledge of range of services can the hospital provide or arrange; only 37 patients answered this question and majority are satisfied with what they know so far (table 3.4.12) or as four patients said that they were comfortable to know about available services the hospital can provide only at appropriate time (i.e. needed). The negative comments were from three patients who knew about help and services hospital can provides either after admission or postoperatively, wished they were informed at earlier stage; and another three patients were not aware of scope of services the hospital can provide and wish to know more.

Patient's satisfaction was positively associated with improved levels of energy/vitality ($r = 0.57$; $n = 25$; $p = 0.003$. $r^2 = 0.34$), pain ($r = 0.6$; $n = 24$; $p = 0.005$. $r^2 = 0.36$) and general health ($r = 0.43$; $n = 25$; $p = 0.031$. $r^2 = 0.19$) in the SF-36 questionnaire, and with general health ($r = 0.53$; $n = 26$; $p = 0.006$. $r^2 = 0.281$) and emotional role ($r = 0.5$; $n = 26$; $p = 0.021$. $r^2 = 0.25$) from the EORTC-C30 questionnaire. Also, patients satisfaction was negatively associated with increased problems with fatigue ($r = -0.6$; $n = 26$; $p = 0.002$. $r^2 = 0.36$), nausea/vomiting ($r = -0.5$; $n = 25$; $p = 0.014$. $r^2 = 0.25$), appetite loss ($r = -0.62$; $n = 26$; $p = 0.001$. $r^2 = 0.384$) and feeling ill ($r = -0.4$; $n = 26$; $p = 0.048$. $r^2 = 0.16$) in the EORTC-C30 questionnaire, and with more problems in swallowing ($r = -0.5$; $n = 26$; $p = 0.011$. $r^2 = 0.25$), speech ($r = -0.42$; $n = 25$; $p = 0.037$. $r^2 = 0.18$) and social contact ($r = -0.54$; $n = 25$; $p = 0.006$. $r^2 = 0.29$) in the EORTC-H&N35 questionnaire.

(9) Nurses support

This question asks patients about help and support from non-doctors hospital staff; 38 patients answered this question and majority (79%) highly rated the help and support provided in the hospital (table 3.4.12). Seventeen patients found nurses in the hospital or at

home were very supportive and believe they would be more than helpful to manage any distressing feeling if needed. However, three patients found nurses support was not enough; one because the clinical nurse specialist was away with no replacement for her at the unit, and another patient wish for the nurse to continue there helpful home visits. Another three patients were informed about the cancer BACUP services by there GPs, and two of them found the local counselors allocated by the cancer-BACUP were very helpful.

Patient's satisfaction was positively associated with better general health ($r = 0.43$; $n = 26$; $p = 0.029$. $r^2 = 0.19$) in the SF-36 questionnaire, and negatively associated with more problems with sexual life ($r = -0.5$; $n = 21$; $p = 0.029$. $r^2 = 0.25$) in the EORTC-H&N35.

(10) Diet services

This question ask patients specifically about diet support and advices provided in the hospital; 36 patients answered this question and majority (77.8%) were satisfied with level of support and help provided in the hospital (table 3.4.12). Few patients feel comfortable to manage their diet with help or advices (two patients); but some others (3-patients) were affected by the limitation for what can be eaten due to the treatment or disease side effects. There were three patients who criticized the hospital food for being not appropriate consistency or not energetic. Another five patients said that they have received diet advices but it was not enough or helpful to them and were forced to develop their own recipes and way of cocking and eating.

Dissatisfaction was less in patient received reconstructive surgery ($\chi^2(2) = 6.8$; $p = 0.034$) and had radiotherapy treatment ($\chi^2(2) = 6.2$; $p = 0.044$).

(11) Respect

This question asks patients if they were felt disrespected by the hospital staff anytime during their treatment; all patients answered this question and majority (92.5%) felt the respect were mutual at all time (table 3.4.12). Few patients felt ignored either for being subjected to a long waiting time in the clinic (4-patients) or as one patient found the nurses treating him different from others for being MRSA positive without being informed way.

(12) Support group

This question asks patients if they were encouraged or had the chance to meet other patients with similar condition; thirty two patients answered this question and only 7 patients (21.9%) were very satisfied for their situation (table 3.4.12). There was contradictory opinion about the role of meeting others with similar situation. Some patients would find meeting people with similar situation is very helpful (7-patients) especially before the operation as expressed by one patient who was introduced to the group after the operation and wished that he knew about it before the operation. Another group of patients knows about the support group but didn't think they will benefit from it (6-patients) or they do see other patients in the clinic but prefer not to speak to others about personal matters (6-patients). There were two preoperative patients who knew about the support group but they were not ready to talk about it at this time, may be at later stage of treatment. The nurses' role in introducing patients to people with similar condition was criticized by patients as some did not think meeting others with similar situation was available (6-patients); while others knew about the support groups but never invited or introduced (3-patients). Some patient felt the need and took the initiative and met people on ward/clinic or neighbors but through their own introduction (5-patients).

Male patients were less satisfied in this question than female patients ($\chi^2(3) = 9.97$; $p = 0.019$); also, patients satisfaction increased with time after treatment ($r_s = 0.6$; $n = 32$; $p = 0.001$. $r^2 = 0.36$). There was a significant association of increased patient's satisfaction with less problems with fatigue ($r = -0.51$; $n = 21$; $p = 0.016$. $r^2 = 0.26$) in the EORTC-C30, and increased problems with mouth opening ($r = 0.44$; $n = 21$; $p = 0.047$. $r^2 = 0.194$).

(13) Managing the look changes

This question asks patients about the support provided for dealing with changes in the look after treatment; only 24 patients answered this question as the rest found it unrelated, and more than half of the patients (54.2%) were very satisfied about level of support provided (table 3.4.12). The main comment was that patient do not feel there is a lot of change in the way they look (15-patients); or they are lucky being alive, and comfortable for the way they looks for their age (4-patients). One preoperative patient was more concerned for her survival than the way she looks. Patients found hospital staff and family/friends and local counselors allocated by the cancer-BACUP were very supportive and (5-patients). However, some patients were more concerned about their body image and reserved on the support provided as some said the issue of dealing with body image changes after surgery was not really discussed and wished he is aware of it and its extent before surgery, and discuss it with professional person (3-patients). There was one patient who felt quite worried at times about it changes in the way he will look even with the support received.

There was a significant association between increased patient satisfaction and higher scores in physical functioning ($r = 0.62$; $n = 17$; $p = 0.008$. $r^2 = 0.384$), role limitation due to physical problems ($r = 0.5$; $n = 17$; $p = 0.047$. $r^2 = 0.25$), role limitation due to emotional problems ($r = 0.9$; $n = 17$; $p < 0.001$. $r^2 = 0.81$), social functioning ($r =$

0.7; n = 17; p = 0.005. r^2 = 0.5), energy/vitality (r = 0.7; n = 17; p = 0.003. r^2 = 0.5), pain (r = 0.6; n = 17; p = 0.016. r^2 = 0.36) in the SF-36 questionnaire; and with physical functioning (r = 0.64; n = 18; p = 0.005. r^2 = 0.41), and social functioning (r = 0.52; n = 17; p = 0.032. r^2 = 0.27) in the EORTC-C30 questionnaire. Also, lower patient's satisfaction was associated with increased problems with social contact (r = -0.6; n = 17; p = 0.016. r^2 = 0.36) and social activity (r = -0.7; n = 15; p = 0.008. r^2 = 0.49) in the EORTC-H&N35 questionnaire.

(14) Sense of control

This question asks patients about help and support provided to maintain control in their life. Thirty four patients answered this question, and more than half of the patients (58.6%) were very satisfied (table 3.4.12). Many patients were very independent and make their own decisions in life (13-patients), some live alone (6-patients) and some with relatives lives in the neighborhood (4-patients). There were three more patients felt the same; however, they found their duties in the house (family or others) keep them focused. Another two patients feels adapted to life after living for long time with the disease (2-patients). Patients stated that family members (5-patients) and medical and nurses staff support especially the clinical specialist nurse (2-patients) was helpful in maintaining sense of control and emotional equilibrium. Nonetheless, their was one patient felt very confused, lost and no one was able to help, and another one find life becoming more difficult and felt very disturbed for that.

Higher patient's satisfaction was associated with lower symptoms of feeling ill (r = -0.53; n = 19; p = 0.021. r^2 = 0.28) in the EORTC-C30 questionnaire, and lower problems with mouth opening (r = -0.65; n = 18; p = 0.004. r^2 = 0.42) in the EORTC-H&N35 questionnaire.

(15) Distressing feelings

This question asks patients about help provided in dealing with distressing feelings. Thirty four patients answered this question and more than half of them (55.9%) highly rated the help provided (table 3.4.12). There were only two patients who felt not distressed, but the majority did and manages it differently. The main support came from family and friends as patients talk to them when distressed (14-patients); another group found the doctors and nurses very supportive when distressed (6-patients); and one patient found the support group helpful. One patient said "patient need to accept to live with cancer and not worried about death, as recurrence is part of the meaning of cancer". A few patients resorted to actions to manage their distress; two patient make them self busy in house work when distressed, another two found meditation through homeopathic therapy and prayers are effective; and one patients plunge into drinking alcohol when distressed. Three patients found nurses support was not enough especially at critical time such as during or immediately after operation or when receiving disappointing news such as incomplete excision.

(16) Going out socially

This question asks patients about support received for going out and about socially. Thirty six patients answered this question and more than half (61.1%) were very satisfied with the support they received (table 3.4.12). There were a number of patients who kept enjoying going out socially with friends and relatives (12-patients); or just stay home as they are not interested in going out socially (2-patients). Nevertheless, there was a number of patients who felt very limited socially because of disease/treatment side effects (9-patients); or patients have no joy in going out due to their mental state as one patient was very confused and worry about the future and another one was depressed due to persistent

sore mouth resulted from LP affecting her mouth. Few patients were limited socially as they do not have close family or friends to go out with (3-patients), and one patient expressed his wishes to have some support or help for going out socially.

There is a trend for less satisfied patients with support for going out socially to be more than 60 years old ($\chi^2(3) = 8.01$; $p = 0.046$), and have lower education level ($r_s = 0.44$; $n = 35$; $p = 0.008$. $r^2 = 0.194$). A high patient's satisfaction was associated with better mental health ($r = 0.42$; $n = 23$; $p = 0.047$. $r^2 = 0.176$) in the SF-36 questionnaire and general health ($r = 0.45$; $n = 24$; $p = 0.027$. $r^2 = 0.203$). Also higher patient's satisfaction was associated with lower speech problems ($r = 0.42$; $n = 23$; $p = 0.049$. $r^2 = 0.18$) in the EORTC-H&N35 questionnaire.

(17) House work

This question asks patients about support in dealing with house work. Thirty five patients answered this question and majority of them (65.7%) are very satisfied with level of support at home (table 3.4.12). Patient found family members very supportive in house work, though sometime not enough (12-patients); and one patient wish to now if help can be arranged through the hospital. Few couples do share housework normally, and patients recognize and appreciate partner help and understanding (7-patients). Another group of patients felt the change after surgery and the difficulty but still coping with house demands (6-patients). Some patients live alone and quite independent (3-patients); however, one patient has relatives livening in the neighborhood and give her whenever possible. There was one patient who can afford to pays for a house maid to help in the house. Patients satisfied with support level for house work tend to have higher education level ($r_s = 0.4$; $n = 34$; $p = 0.023$. $r^2 = 0.16$).

(18) Family support

This question asks patients about the family support received. Thirty eight patients answered this question and majority (84.2%) of patients fined family members were very supportive (table 3.4.12). However, six patients are living alone but two of them are frequently visited by other family members.

Higher patient satisfaction was associated with higher level of patient education (r_s = 0.4; n = 37; p = 0.016. r^2 = 0.16), better global health (r = 0.4; n = 25; p = 0.048. r^2 = 0.16) in the EORTC-C30 and lower depression scores (r_s = -0.44; n = 25; p = 0.028. r^2 = 0.194). Also, lower patients satisfaction was associated with high nausea/vomiting symptoms (r = -0.4; n = 25; p = 0.049. r^2 = 0.16), high dyspnoea symptoms (r = -0.43; n = 25; p = 0.03. r^2 = 0.185) in the EORTC-C30 questionnaire, and with high symptoms of feeling ill (r = -0.53; n = 25; p = 0.006. r^2 = 0.28) in the EORTC-H&N35 questionnaire.

(19) Friends support

This question asks patients about the support they received from friends and relatives. Thirty eight patients answered this question and majority of patients (78.9%) find friends were very supportive (table 3.4.12); some patients are not involving their friends fully at this time (3-patients) and one patient lives alone with no family or friends.

High patient satisfaction was associated with increased education level (r_s = 0.54; n = 37; p = 0.001. r^2 = 0.29), with lower depression scores (r_s = -0.43; n = 26; p = 0.028. r^2 = 0.185), with better mental health (r = 0.46; n = 25; p = 0.02. r^2 = 0.213), and with higher global health (r = 0.52; n = 26; p = 0.007. r^2 = 0.27). Also, lower patient's satisfaction was associated with higher symptoms of nausea/vomiting (r = -0.5; n = 25; p = 0.011. r^2 = 0.25), with higher symptoms of dyspnoea (r = -0.57; n = 26; p = 0.002. r^2 = 0.325), with more problems of senses (r = -0.48; n = 25; p = 0.016. r^2 = 0.23), with more trouble with social

eating ($r = -0.52$; $n = 24$; $p = 0.009$. $r^2 = 0.27$), and with increased symptoms of feeling ill ($r = -0.63$; $n = 26$; $p = 0.001$. $r^2 = 0.4$).

(20) Financial advices

This question asks patients about support and advices received in dealing with financial matters. Twenty eight patients answered this question and patients here split into mainly two groups (table 3.4.12), one group believes support provided in the hospital was very satisfactory (35.7%) and another group believes that support was poor (32.1%). There were many patients believe that financial help and advices from hospital are not needed (16-patients), and another two patients benefited from hospital support as one patient got some financial advices in radiotherapy department, and another patient had the treatment covered by the insurance company and personal allowance was arranged while under treatment. On the other hand, there were some patients on benefits or disability advantages or relay on savings and majority of them expresses their wishes for financial support or someone to discuss financial matters with and believe that the financial support was not provided or not enough in the hospital (20-patients). There were two patients who relied on charity for sometime before they are back to full time job.

There was a trend for patient satisfaction with support and advice services in the hospital to increase with increase in income level as perceived by patient ($\chi^2(6) = 11.9$; $p = 0.065$) and to decrease in smokers ($\chi^2(3) = 7.8$; $p = 0.05$).

(21) Time for self or prayers

This question asks patient if they have enough time for them to enjoy or do their own prayers. All patients answered this question and the majority (85%) is very satisfied with the amount of quality time they enjoy (table 3.4.12). Patients are divided into three types; one that is not religious but do have a good amount of time for them self (6-patients);

another group practice homeopathic meditation (3-patients); and a third religious group of patients who pacify them self through frequent prayers (4-patients). The other group of patients who do not enjoy a satisfactory time for themselves as they are busy with housework and kids at home (2-patients) or with office work (1-patient). One preoperative patient felt very confused and in constant worry therefore does not enjoy anytime for her self when alone.

(22) Spiritual advisor

This question asks patients about the support from a spiritual figure or advisor. Twenty six patients answered this question and majority (69.2%) was satisfied with their spiritual needs (table 3.4.12). Some patients were aware of this service at the hospital as they were offered spiritual advisor by the nurses on admission (3-patients); however, many patients were not religious or spiritual and did not felt the need for a spiritual advisor (11-patients). Another group of patients who believe in holistic practices either practiced homeopathic meditation (4-patients) or see one of their friends/relatives as a spiritual advisor (5-patients).

Dissatisfaction was mainly in patients received with segmental bone resection ($\chi^2(3) = 11.2$; $p = 0.011$).

(23) Future Hopes

This question asks patients about their future hops and morals. All patients answered this question and most of them (60%) were very optimistic (table 3.4.12). Some patients were realistic about their future (2-patients), and some lives the day when possible (3-patients). One patient gets support from her prayers, and another patient is happy to be alive as long as the kids' future is secured. However, there were few patients who are not

sure and worry about their future depending on their recovery from treatment received (5-patients) as one patients said the side effects of treatment are constant remainder of cancer.

There is a trend for patients with high hopes for the future to be employed ($\chi^2(3) = 7.3$; $p = 0.06$). High level of hope was associated with better physical functioning ($r = 0.44$; $n = 26$; $p = 0.025$. $r^2 = 0.194$), with better role limitation due emotional problems ($r = 0.44$; $n = 26$; $p = 0.026$. $r^2 = 0.194$), with better mental health ($r = 0.4$; $n = 26$; $p = 0.044$. $r^2 = 0.16$) in the SF-36 questionnaire, with better global health ($r = 0.57$; $n = 27$; $p = 0.002$. $r^2 = 0.325$), with better physical functioning ($r = 0.46$; $n = 27$; $p = 0.016$. $r^2 = 0.217$), and with cognitive functioning ($r = 0.48$; $n = 27$; $p = 0.012$. $r^2 = 0.23$) in the EORTC-C30 questionnaire. Also, lower future hopes were associated with worse symptoms of fatigue ($r = -0.54$; $n = 27$; $p = 0.003$. $r^2 = 0.29$), with worse pain symptoms ($r = -0.43$; $n = 27$; $p = 0.026$. $r^2 = 0.185$), with worse dyspnoea symptoms ($r = -0.56$; $n = 27$; $p = 0.002$. $r^2 = 0.314$), with worse insomnia symptoms ($r = -0.38$; $n = 27$; $p = 0.047$. $r^2 = 0.14$) in the EORTC-H&N35, with increased problems with speech ($r = -0.42$; $n = 26$; $p = 0.034$. $r^2 = 0.18$), and with increased symptoms of feeling ill ($r = -0.43$; $n = 27$; $p = 0.026$. $r^2 = 0.185$) in the EORTC-H&N35 questionnaire.

3.4.5 Care-giver interview results

(1) Confidence in the doctor

Most care-taker are confident in the doctors; the only two comments reported were by two care-takers, one said he has yet some un-answered questions and anther one think that there is lack of communication during the consultation.

(2) Clear honest Information

On the issue of information communicated during the consultation there were two comments; one care-taker felt that there was no opportunities for care-taker to raise questions, and the other one think some information were omitted though most important information have been conveyed.

(3) Sensitivity

There was one care-giver who thinks there is a lot of "gloom and doom" from oncology, and another care-taker felt very worried when the biopsy result was delivered by a new senior registrar (SPR) and the treating consultant was a way.

(4) Choice of treatment

There was one care-taker who wished to have voiced her opinion even though patient doesn't want to, and another care-taker patient was comfortable to set as advisor only and leave it to the patient to decide.

(5) Side effects

There were four care-taker who were not happy for the way or the amount of information they had on side effects; one felt they had to extract information, one had to go and search the internet himself for information many time, one wished for information sheet about radiotherapy side effects (short + long), and one want more information further

down the line after chemotherapy. One care-taker said doctors are readily available when something occurs though not all side effects were given.

(6) Time of the appointment

There was one care-taker who feels that doctors are always under pressure with time and they were "shunted off" at times.

(7) Other information sources

Although few care-takers expressed their satisfaction with information provided by doctors only (2-patients) many others did not. One care-taker believes that more information material in the department is required; book for children, alternative therapies and how to contact cancer counselling trusts. Another two care-takers wished they have been provided with people addresses, websites or organizations for more information, or at least offered a second opinion. One care-taker already used cancer BACUP for more information and support.

(8) Advice on services

There were two care-givers who made use of the clinical nurse specialist (CNS) for coping with diagnosis, but one of them tried in vein to organize alternative therapy but staffs were unable to help; and both think a local or in-house counsellor would help. One care-giver wished to know more about kind of support can be arranged to patient at home, and another felt bitter for lack of continuity of nursing services at home; another care-giver was not able to make advantage of hospital transport services due to the long distance travelled and the hospital transport dose not cover that distance.

(9) Nurses Support

Care-givers have a mixed experience with nurses; one care giver has a good experience with nurses especially the Macmillan nurse, while another one find nurses at home are not helpful comparing to nurses in the unit. One care-giver received minimal

support at diagnosis from nurses and another one the language barrier with nurses is a limiting factor. One care-giver had difficulty with some individuals; however, happy with overall care.

(10) Diet advices

Two care-givers were disappointed by the food provided at the hospital and expressed their need for more advices on food preparations for patient to share on table. One care-giver suggests producing a cookery book for basic modified food to oral cancer patients.

(12) Meeting similar others

Care-givers made different comments on the issue of support group and meeting others with similar condition. One care-giver finds it sometime helpful and sometime depressing, as another one said many other patients' opinions are not encouraging. There was one care-giver who believes on the benefits of support group, however, sees the presence of good family support will reduce the need for attending the support group. Another care-giver attends with his wife to the support group but tend to shy away from talking to others. There were two care-givers wished to meet other patients' relatives (like their partners who spoke with other cancer patients) but there was no chance (or offer) to do that. One care-giver wished for his children to meet with other children in a similar situation.

(13) Managing the look changes

Regarding dealing with changes on the patient look, there were two patients who were informed about changes might happen but not offered any support. One care-giver finds family members supportive, and another one was aware of the available support in the local health centre from previous hospitalization. There was one care-giver who noticed

people reaction and want advices on how to help others with changes in the patient look especially children.

(14) Sense of control

Care-givers try to keep sense of control as much as possible, some believe that family and job demands keep them focused (1-patient), some struggle at times (1-patient), some felt the increase in responsibilities at home as they consider the patient's health is a priority (2-patient), and some is feeling burn-out with time in long survivors (the continuous demand such as feeding ...etc). One care-giver finds it is difficult when events takes place but was able to regain control after a while; also not enough information at time results in lack of control. One care-giver finds it difficult when patient do not want to talk.

(15) Distressing feelings

Care-givers find family members helpful in dealing with distressing feelings (2-patients), and some find the information at the clinic helpful (1-patient); one care-giver deal with thing together with patient. There was one patient who was astounded that there is no in-house counsellor as she have used cancer-counselling trust (9-sessions per person), and wish to see a specialist counsel who knows about head and neck cancer. However, at the same time there was one care-giver who declined professional help.

(16) Going out socially

There were few patients who do not go out socially that frequently, some because they adapt to changes in their life (2-patients) or deal with things together with patient (1-patient), some because they are reluctant to go out as they feel very limited due to the extra responsibility (3-patients). One care-giver was thankful to his friends as they helped him to go out and believe that it is important to have social time within hospital setting.

(17) House work

There were four care-givers who do not feel the need for help as they manage things well at home on their own or with their partner; another one find the support from other family members helpful. There was one patient who finds it extremely difficult to keep up and maintaining a sense of order, but he welcomes any help.

(18) Family support

There were three care-givers who valued the presence of close family circle and their help.

(19) Friends support

Few care-givers have a good circle of friends/neighbours to them and the patients; but not all friends are involved, those with previous experience of cancer are more helpful (4-patients). One care-giver was more guarded about the cancer issue and not fully involving friends at this time.

(20) Financial advices

Few care-givers said the issue of financial support or benefits was not discussed before or don't know anything about it and wish to talk to someone about it (4-patients). On care-giver was on pensions, and another one think it may have become more an issue if his work time had to change.

(21) Time for your self

Few care-givers were able to continue activities but not to the same degree, as responsibilities becoming more and demanding; but adapted living with cancer (4). Another care-giver finds time in her daily prayers. There was one care-giver who said she will not rest until her sister (the patients) gets better. There was one care-giver who supports the idea of having cancer counselling trust and alternative therapy sessions.

(22) Spiritual advisor

Seeing a spiritual advisor was not a priority for one care-giver; however, another care-giver believes a counsellor or a spiritual advisor would have been helpful. Sometime religious believes and prayers can be the best support as stated by one care-giver.

(23) Future Hops

Care-givers find doctors very positive and they reciprocate (2-patients); others being more realistic and deal with thing when it occur (2-patients). One care-giver said "Hops swing like a pendulum, difficult to know what to feel apart from scared"; however, find a booklet or counselling following treatment on how to deal with feelings would help.

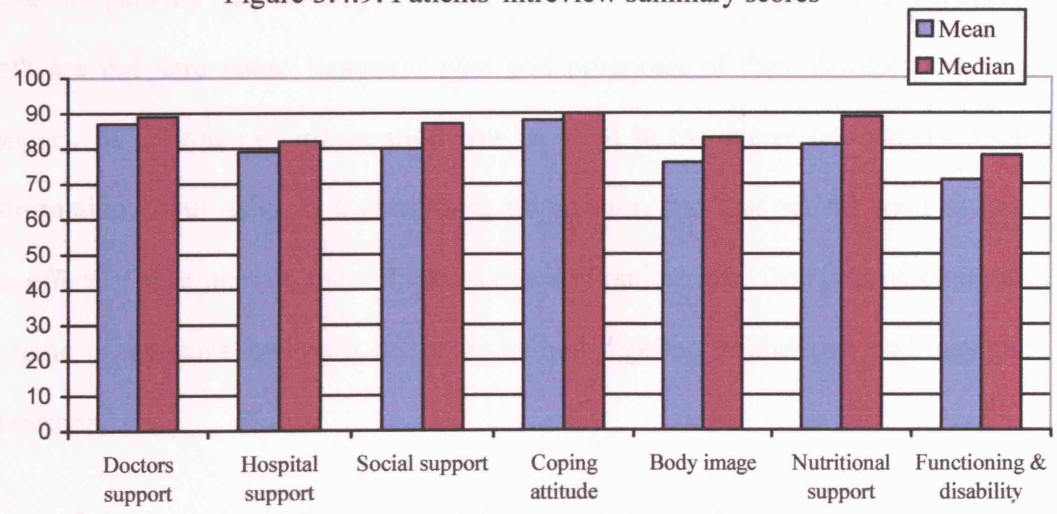
3.4.6 Patients interview summary

Patient's scores from the interview questions are summarized under 7 major domains (table 3.4.1), and a summary score produced (table 3.4.13).

Table 3.4.13: Summary of patients psychosocial support scores

Psychosocial support domains	median	mean
Doctors support	89	87
Hospital support	82	79
Social support	87	80
Coping	90	88
Body image	83	76
Nutritional support	89	81
Functioning & Disability	78	71

Figure 3.4.9: Patients' intreview summary scores



3.4.6.1 Doctors' support:

In this subject, the focus was on patient satisfaction with doctors' support and information provided during the consultations; the issue was discussed from the aspects of patient confidence in doctors, having clear honest information, doctors' sensitive attitude, choices of treatment, side effects, and appointment time management. The overall score for this aspect of support was high with a mean score of 87%.

Many patients stated that without this confidence in doctors they will not come back to this hospital (5 patients). Also, one patient found that the use of new technology in treatment of cancer (such as PDT) is important factor for the strong confidence in doctors. Nevertheless, a delay in the diagnosis of osteo-sarcoma after several resections let one patient questioning the credibility of his doctors.

Another factor that affects patient's satisfaction with consultation is how clear the information communicated during the consultation. The main comment from patients was that a lot of information was given at once, and that was confusing (3-patients). Also there were two patients who developed cancers as a consequence of pre-malignant condition and both are not sure about treatment plan and prognosis of their disease (cancer and pre-cancer). A shortage of information was reported in two areas; one patient wanted more information about medical investigating procedures, and one patient want to know about the effect of treatment on the different aspects of patient life. One patient would have liked a name of someone he could call once he had digested information and may have some questions.

It is psychologically important for patients to conduct communication with doctors who are sensitive and caring for the patient's emotions. Again, the main comment from patients was that a lot of information was given at once, and that was overwhelming (3-

patients). The other comment was on the way of breaking bad news; two patients said the biopsy results was delivered bluntly, and one patient was not introduced to the people in the room when received the biopsy results in the MDT clinic. Also, one patient criticized the doctors for not assessing her education level (patient was illiterate) and communication at the period directly after operation was a major problem could have been avoided.

In the issue of patients having choices of treatment; 4 patients felt that they have discussed the treatment plan offered thoroughly and made there decision; while 8 patients believed they had not been offered alternative treatments and took what was offered. Another 10 patients decided to trust the doctors for what is best for them; the reason for that put forewarned by some patient is that they doubted their ability to take the correct decision and there wasn't much time to think (3-patients).

In the subject of treatment side effects, the main comment was that patients had the information but not realizing the magnitude of treatment side effects until experience it or postoperatively, much more than imagined. Also, doctors concerned more about long term ones but not the immediate ones (11-patients). Another group of patient said that they were not fully aware of the treatment consequences/side effects, only told about serious ones (8-patients). There were two patients who found side effects are shocking, distressing and confusing when it happened even when patient knows about it. Some other patients were more relaxed about the issue of treatment side effects as one patient said he deals with complications when it happens, day to day; and another one did not want a lot of information.

Regarding appointment time, the only comment was the long waiting time in the clinic setting in a small inconvenient space, and the meeting with the doctors could only last for 5-min sometime (7-patients).

3.4.6.2 Hospital support:

This subject focused on patients' satisfaction with hospital services including dietician support, speech therapist support, nurses support (in the clinic, hospital or at home), receptionist, technicians, or transportation, managing distressing feelings, changes in the look and financial difficulties; The level of satisfaction was generally good with a score of 79%.

Nurses are significant source of information to cancer patients by providing information directly or providing patients with supplementary information material or guiding patients to other sources of information. Twenty five patients who said that they had received only verbal information from the doctors; 10 of them said other information sources are not needed (10-patients). Another 6 patients said information from sources other than doctors may be confusing and could complicate things; and two patients find it inappropriate to give leaflets for serious disease like cancer (serious, frightening, complicated information in easy, reassuring manner). There were 6 patients who were provided with information leaflets from nursing staff, and one patient said leaflets are available at the rack in the MFU. Nevertheless there were 6 patients who were not satisfied with level of information and they looked for more on the internet, from friends, other doctors, and magazines; and wish there was some direction for internet sources. One patient was of concern as none of the staff known she was illiterate; therefore, available source for additional information was not suitable.

For help and advices about services the hospital can provide to the patients there were three patients who knew about it either after admission or postoperatively and wished they were informed at earlier stage; another three patients were not aware of scope of services the hospital can provide and wish to know more. However, four patients were comfortable to know about available services the hospital can provide only at the appropriate time (i.e. needed).

Many (17-patients) found nurses in the hospital or at home were very supportive and believe they would be more than helpful to manage any distressing feeling if needed. Three patients found nurses support was not enough; one because the clinical nurse specialist was away with no replacement for her at the unit, and another patient wish for the nurse to continue there helpful home visits. Another three patients were informed about the cancer BACUP services by there GPs, and two of them found the local counselors allocated by the cancer-BACUP were very helpful.

In the subject of diet advices from the dietician or nurses many patients were satisfied with information provided. There was two patients who managed well without advices; but another five patients said that they have received diet advices but it was not enough or helpful to them and were forced to develop their own recipes and way of cocking and eating.

All patients felt the respect was mutual with hospital staff. Few patients felt ignored for being subjected to long waiting time in the clinic (4-patients) and one patient was treated differently from others without proper explanation when he was tested positive for MRSA by the nurses.

Many patients knew about the support group either from the nurses or the sticker in the waiting area; however, the nurses' role in introducing patients to people with similar condition was criticized as some patients did not think meeting others with similar situation

was available (6-patients); while others knew about the support groups but never invited or introduced (3-patients). Some patient felt the need and took the initiative and met people on ward/clinic or neighbors but through their own introduction (5-patients).

Patients found hospital staff and family/friends and local counselors allocated by the cancer-BACUP were very supportive and (5-patients). However, some patients were very concerned about their body image and more reserved on the support provided as some said the issue of dealing with body image changes after surgery was not really discussed and wished to know it and its extent before surgery, and wished to discuss it with professional person (3-patients). There was one patient who felt quite worried at times about changes in the way he look even with the support received.

For maintaining sense of control, many patients found the support from medical and nurses staff especially the clinical specialist nurse was helpful in maintaining sense of control and emotional equilibrium. Nonetheless, there were one preoperative patient who felt very confused and lost, and no one is able to help; and another postoperative patient who believes life becoming more difficult and felt very disturbed.

Cancer or its treatment usually causes distressing feeling and patients deal with distress in different ways. Only two patients felt not distressed, but the majority did and manages it mainly thorough support from family and friends as patients talk to them when distressed (14-patients). Some patients found the doctors and nurses very supportive when distressed (6-patients); and one patient found the support group helpful. One patient said "patient need to accept to live with cancer and not worried about death, as recurrence is part of the meaning of cancer". A few patients choose to take action to manage their distress, two patient make themselves busy in house work when distressed; another two found meditation through homeopathic therapy and prayers are effective; and one patients plunge himself into drinking alcohol when distressed. Three patients found nurses support was not

enough especially at critical time such as during or immediately after operation or when receiving disappointing news such as incomplete excision.

Many patients believe that financial help and advices from hospital are not needed (16-patients) and two patients benefited from hospital support as one patient got some financial advices in radiotherapy department, and another patient had the treatment covered by the insurance company arranged by the hospital staff and personal allowance was provided while under treatment. Nonetheless, there were many patients who believe that the financial support was not provided or not enough in the hospital (20-patients).

3.4.6.3 Social support:

This subject focused on supports to the patient from the community, these include support from other people with similar condition, support from family or friends to go out and about socially and support from the spiritual figures in patient life. The level of patients' satisfaction with social support was high with score of 80%.

However, there was a conflict among patients on the role of meeting others with similar situation. Some patients would find meeting people with similar situation very helpful (7-patients) especially before the operation as expressed by one patient introduced to the group after the operation and wished that he knew about it before the operation. Also, few patients who found it helpful met people in the ward or while waiting to be seen in the clinic or from the neighbors (5-patients). Another group of patients knows about the support group but didn't think they will benefit from it (6-patients) or they do see other patients in the clinic but preferred not to speak to others about personal matters (6-patients). The two preoperative patients knew about the support group but they were not ready to talk about it now.

The role of social activity in providing social support was demonstrated in the positive attitude of many patients who still enjoy going out socially with friends and relatives (12-patients); and in those patients who felt very limited socially because of the disease or the treatment side effects (9-patients). Also, patient's mental state can cause a significant social limitation as expressed by two patients who have no joy in going out one because she was very confused and worry about the future and the other because she was depressed due to her persistent sore mouth resulted from LP. A few patients do not enjoy the accessibility to different options of social activity as they do not have close family or friends to go out with (3-patients). One patient expressed his wishes to have some support or help for going out socially. It is important to note that there are patients who are satisfied with limited social activities as expressed by two patients who were not interested in going out socially.

Many patients find family members (17-patients) and friends (16-patients) were very supportive (17). However, some patients live alone (6-patients) and some are frequently visited by other family members (2-patients). Some of the patients do have friends but they are not involving them at this time as they do not want to be treated differently by their friends.

Spiritual support also plays a role in the community social support to patients. This service is offered by the hospital as mentioned by some patients when they were told about it by the ward nurses upon their admission (3-patients); however, many patients were not religious or spiritual and did not felt the need for a spiritual advisor (14-patients). Another group of patient who believe in holistic practices and either practiced homeopathic meditation (4-patients) or see one of their friends/relatives as a spiritual advisor (5-patients).

3.4.6.4 Coping support:

This issue was discussed from the aspect of patients' confidence in doctors, patients' sense of control on their life, the enjoyment of private time during the day and future hopes opinion; and the result was generally high with a score of 88%).

Maintaining sense of control is an indicator of good coping with the disease. Feeling independent from others and making your own decisions give patients a good sense of control as expressed by many patients (13-patients). Also, living alone and manage your own needs will give feeling of independence as mentioned by some patients who live alone (6-patients) or alone but with relatives in the neighborhood (4 patients). There are few independent patients who cope with stress by using their daily routine duties in the house (family or others) to keep them focused (3-patients). Some of the long survivors felt adapted to life after living for long time with the disease (2-patients). One has to appreciate the support provided by others such as family members (5-patients), and doctors and nurses (2-patients) in maintaining sense of control and emotional equilibrium. Confidence in doctors is an important supporting factor for coping as expressed by some patients who felt that without this confidence in doctors they will not come back to this hospital (5-patients). However, there was two patients who need support to cope as one felt confused and lost and alone with no one able to help and anther one who felt burn out and disturbed as he find life becoming more difficult.

One of the indictors of good coping is to enjoy a time for your self; and many patients interviewed do enjoy a good amount of time. They were of three types, one that is not religious but do have a good amount of time for them self (6-patients); another group find a good time for themselves in practicing homeopathic meditation (3-patients); and a third religious group who comfort themselves through frequent prayers (4-patients). On the

other hand there are patients who does not enjoy a satisfactory time for themselves as they are busy with housework and kids at home (2-patients) or with office work (1-patient). One preoperative patient felt very confused and in constant worry therefore does not enjoy anytime for her self when alone.

Patients who copes will with disease are likely to have a positive attitude about future. Majority of the patients were very optimistic about future, some were realistic (2-patients), and some live (enjoy) the day when possible (3-patients). One patient feels the support from her prayers; another patient is happy to be alive as long as the kids' future is secured. There were few patients who are not sure and worry about the future depending on their recovery from treatment received (5-patients) as one patient said the side effects of treatment are constant remainder of cancer.

3.4.6.5 Support for body image changes:

This issue was discussed from the aspects of support to patient to maintain body integrity and sense of control, and the patients' ability to go out socially; and the patients' satisfaction was high with a score of 76%.

Body image has a significant role in enhancing self confidence and sense of control. Also, sense of control is affected by the level of independence patients' feel. Patients found hospital staff and family/friends and local counselors allocated by the cancer-BACUP workers were very helpful in dealing with changes in the way they look and in maintaining senses of self confidence (12-patients). However, many patients did not feel that there is a lot of change in the way they look (15-patients); or felt they are lucky of being alive, and comfortable for the way they look for their age (4-patients). This attitude was demonstrated in one preoperative patient who was more concerned for her survival more than she looks. Also, being independent as many patients felt (15-patients) or living alone

with or without relatives living nearby (10-patients) is an indication of self confidence; patients continue to go out socially with friends and relatives have more confidence in them self and less affected by changes to their body image (12-patients). The significant effect of changes in body image imposed on patients' life was mitigated by adaptation in long survivors (2-patients) or in patients who have no interest in going out socially (2-patients).

There were few patients who were worried and concerned about their body image (4); some of them wish they knew about the possibility of body changes and its extent before surgery, and now wish to discuss it with a professional person (3-patients). Others felt very limited socially as a result of changes occurred after treatment which reflected on their body image as a whole (9-patients). There was one patient who felt depressed due to her persistent sore mouth resulted from LP which limits her choices of what to eat and drink socially.

3.4.6.6 Nutritional support:

This issue was discussed from the aspects of support provided from the dietician at the hospital, from the support provided to go out socially and eat, from the ability of patient to self care or doing the house work; and patients were satisfied with a score of 81%.

Going out socially and enjoying a meal or a drink improve patients' nutritional status. This is because when patient go out with someone there is a good indication that patients will be better psychologically and may enjoy a good meal as well. Family and friends play an important role in encouraging patients to do so. There are few patients who felt limited socially as they do not have close family or friends to go out with (4-patients), but many others continue the joy of going out socially with friends and relatives (12-patients). Nevertheless, there are few patients who are not interested in going out socially (2-patients).

On the other hand some patients who continue to endure the suffering as consequences of the treatment are limited in their social activity (9-patietns), which indirectly may lead them to social isolation and/or more psychological problems. Mental condition has a strong relation with social activity as demonstrated by two patients who have no joy in going out as one patient was very confused and worried about the future and the other was depressed due to persistent sore mouth resulted from LP.

The dieticians in the hospital provide advices and support for cancer patients as the treatment may cause some limitation for what can patient eat. There were two patients who were not affected much by the treatment received as they managed well without advices from hospital staff (2-patients); but, other patients (3-patients) felt the limitation for what can be eaten and managed well the help of the dietician. However, there were five patients who received diet advices but believe it was not enough or helpful to them and were forced to develop their own recipes and way of cocking and eating. Another group of patients criticized the hospital food for being not in the appropriate consistency for them to eat it or not energetic enough (3-patients).

Cancer patients may feel a drop in their energy level after treatment and a contributing factor to this situation is the decrease in the nutritional support. This was recognized on the appreciation of many patients for their partners or other family members understanding and support in house work (21-patients). Some other patients are struggling but continue to cope with house demands (6-patients). Few patients live alone and feel quite independent in their life and manage their own house work by themselves (3-patietns). There was one patient who was financially well enough to employ a house maid to help in house work.

3.4.6.7 Functioning and disability

This issue was discussed from the aspects of support to patient for having sense of control, from support to patient in doing house work, and from the support in financial problems; and patients were satisfied with a score of 71%.

Many of the patients interviewed were very independent in their life and make their own decisions (16-patients); also, some patients live alone (6-patients) and some with relatives lives in the neighborhood (4-patients). Another two patients feels adapted to life after living for long time with the disease. This independency and adaptation to life indicates that patients are not disabled as such, to interfere with their daily activity. At the same time, many patients valued the support provided by family members (5-patients) and medical/nurses staff (2-patients) in helping patients to overcome their difficulties and maintaining this sense of control in their life. However, there was one patient who is disturbed for his life becoming more difficult with time.

Support from family members in house work does help in easing patients' disability, and many patients found family members are very supportive in house work, though sometime not enough (14-patients). Also, there were few couples who share housework normally, but patient appreciate partner help and understanding (7-patients). Another group of patients felt the change after surgery and the difficulty but manage to cope with house demands (6-patients). However, some patients live alone and manage their own life independently. It is interesting that one patient overcome her problem by employing a house maid to do the house work.

One of the problems associated with cancer patients is the financial difficulties during and after treatment. This issue becoming increasingly more important as oral and pharyngeal cancer is increasing in pre-retirement age population. The hospital does

provide financial advice services and support when possible. However, many patients did not need any financial help or advice from hospital (17-patients); and others did benefited from hospital support as one patient got some financial advices in radiotherapy department, and another patient had his treatment covered by the insurance company with personal allowance while under treatment. On the other hand, there were many patients relayed on their benefits or disability advantages or on their savings during and after treatment and majority of them wished they had some help or at least advices on financial matters at that time (20-patients). Two patients were relying on charity for sometime before they are back to full time job.

3.4.7 Correlations analysis:

3.4.7.1 Summary scores correlation with patients' demographics and HADS scores

The summary scores were correlated to some of patients' demographics and patients' HADS scores (table 3.4.14). There were strong correlations between increased patient satisfaction with doctor's support and length of time after treatment ($r = 0.53$; $n = 40$; $p < 0.000$. $r^2 = 0.28$), and between increased patient satisfaction with social support and increased education level ($r = 0.45$; $n = 39$; $p = 0.004$. $r^2 = 0.203$), and between increased patient's satisfaction with nutritional support and being younger patients ($r = -0.41$; $n = 39$; $p = 0.009$. $r^2 = 0.17$). Also, there were associations between increased patient satisfaction of social support with increased time after treatment ($r = 0.32$; $n = 40$; $p = 0.045$. $r^2 = 0.103$), and with lower depression scores ($r = -0.47$; $n = 27$; $p = 0.014$. $r^2 = 0.22$); between higher patient satisfaction with body image and lower anxiety score ($r = -0.42$; $n = 27$; $p = 0.03$. $r^2 = 0.18$); and between increased patient satisfaction with nutritional support and increased education level ($r = 0.33$; $n = 38$; $p = 0.043$. $r^2 = 0.11$). There were trends for association between increased patient satisfaction with hospital services and increased time after surgery ($r = 0.28$; $n = 40$; $p = 0.08$. $r^2 = 0.08$); and between better patient coping and higher anxiety scores ($r = 0.33$; $n = 27$; $p = 0.09$. $r^2 = 0.11$); and between higher patient satisfaction with nutritional support and lower depression scores ($r = -0.35$; $n = 27$; $p = 0.08$. $r^2 = 0.12$).

Table 3.4.14: Correlation of patient's summary scores with patient's demographics and HADS scores

		patient's age	education level	income level	stage of treatment	anxiety	depression
Doctors support	r	.008	-.212	-.222	.531	-.346	.153
	Sig.	.960	.195	.175	.000	.077	.446
	N	40	39	39	40	27	27
Hospital support	r	.040	-.011	-.177	.281	-.316	-.049
	Sig.	.805	.946	.282	.079	.108	.808
	N	40	39	39	40	27	27
Social support	r	-.063	.450	.029	.319	-.260	-.468
	Sig.	.701	.004	.862	.045	.190	.014
	N	40	39	39	40	27	27
Coping	r	.051	-.185	-.069	.167	-.330	-.076
	Sig.	.753	.258	.676	.303	.093	.708
	N	40	39	39	40	27	27
Body image	r	-.114	-.079	-.087	.160	-.418	-.121
	Sig.	.482	.633	.597	.325	.030	.548
	N	40	39	39	40	27	27
Nutritional support	r	-.412	.330	-.070	-.072	-.287	-.345
	Sig.	.009	.043	.675	.661	.146	.078
	N	39	38	38	39	27	27
Functioning /Disability	r	-.065	.020	-.227	.025	-.317	-.110
	Sig.	.701	.909	.183	.882	.131	.610
	N	37	36	36	37	24	24

3.4.7.2 Summary scores correlation with SF-36 scores

The patients' summary scores were also correlated with patients' scores in the SF-36 quality of life questionnaire (table 3.4.15). There was a trend for patient satisfaction with doctors' support to increase with lower limitations due to emotional problems ($r = 0.36$; $n = 26$; $p = 0.08$. $r^2 = 0.13$). Increased patient satisfaction with hospital services associated with higher physical functioning ($r = 0.41$; $n = 26$; $p = 0.04$. $r^2 = 0.17$), with lower limitation due to physical problems ($r = 0.41$; $n = 26$; $p = 0.03$. $r^2 = 0.17$), with lower limitations due to emotional problems ($r = 0.5$; $n = 26$; $p = 0.01$. $r^2 = 0.25$), with better social functioning ($r = 0.4$; $n = 26$; $p = 0.03$. $r^2 = 0.16$), with better mental health ($r = 0.4$; $n = 26$; $p = 0.03$. $r^2 = 0.16$), with increased energy/vitality ($r = 0.5$; $n = 26$; $p = 0.01$. $r^2 =$

0.25), and with better pain control ($r = 0.4$; $n = 25$; $p = 0.05$. $r^2 = 0.16$). Increased patient satisfaction with social support was associated with better mental health ($r = 0.4$; $n = 26$; $p = 0.05$. $r^2 = 0.16$); however, only a trend for positive association between patient satisfaction with social support and pain control ($r = 0.4$; $n = 25$; $p = 0.07$. $r^2 = 0.16$). Better coping attitude was associated with lower limitations due to emotional problems ($r = 0.4$; $n = 26$; $p = 0.03$. $r^2 = 0.16$); however, there was a week positive association between patient coping and physical functioning ($r = 0.34$; $n = 26$; $p = 0.09$. $r^2 = 0.12$). Increased patients satisfaction with body image was associated with physical functioning ($r = 0.6$; $n = 26$; $p = 0.001$. $r^2 = 0.36$), with lower limitation due to physical problems ($r = 0.5$; $n = 26$; $p = 0.02$. $r^2 = 0.25$), with lower limitations due to emotional problems ($r = 0.63$; $n = 26$; $p = 0.001$. $r^2 = 0.4$), with better social functioning ($r = 0.53$; $n = 26$; $p = 0.005$. $r^2 = 0.28$), with better mental health ($r = 0.43$; $n = 26$; $p = 0.03$. $r^2 = 0.19$), and with increased energy/vitality ($r = 0.5$; $n = 26$; $p = 0.02$. $r^2 = 0.25$). Increased patient satisfaction with nutritional support was associated with lower limitation due to physical problems ($r = 0.42$; $n = 26$; $p = 0.03$. $r^2 = 0.18$), and with better mental health ($r = 0.4$; $n = 26$; $p = 0.04$. $r^2 = 0.16$); however, there was a positive trend for patient satisfaction with nutritional support and physical functioning ($r = 0.4$; $n = 26$; $p = 0.066$. $r^2 = 0.16$), and lower limitation due to emotional problems ($r = 0.4$; $n = 26$; $p = 0.07$. $r^2 = 0.16$). Higher patient satisfaction with functioning and disability was weekly associated with lower limitation due to emotional problems ($r = 0.4$; $n = 23$; $p = 0.06$. $r^2 = 0.16$), and with better mental health ($r = 0.4$; $n = 23$; $p = 0.06$. $r^2 = 0.16$).

Table 3.4.15: SF-36 scores correlation with patient's summary scores

		PF	RP	RE	SF	MH	EV	PA
Doctors support	R	.133	.278	.355	.099	.175	.209	.183
	Sig.	.518	.169	.076	.629	.393	.304	.380
	N	26	26	26	26	26	26	25
Hospital support	R	.406	.426	.498	.434	.421	.480	.402
	Sig.	.040	.030	.010	.027	.032	.013	.046
	N	26	26	26	26	26	26	25
Social support	R	.217	.301	.101	.257	.395	.292	.368
	Sig.	.287	.135	.624	.205	.046	.147	.070
	N	26	26	26	26	26	26	25
Coping	R	.342	.195	.419	.233	.314	.293	.098
	Sig.	.088	.339	.033	.252	.118	.147	.641
	N	26	26	26	26	26	26	25
Body image	R	.601	.450	.628	.529	.427	.454	.223
	Sig.	.001	.021	.001	.005	.030	.020	.285
	N	26	26	26	26	26	26	25
Nutritional support	R	.365	.419	.361	.320	.411	.168	.113
	Sig.	.066	.033	.070	.111	.037	.411	.590
	N	26	26	26	26	26	26	25
Functioning /Disability	R	.303	.258	.395	.228	.395	.234	.023
	Sig.	.159	.235	.062	.296	.062	.283	.917
	N	23	23	23	23	23	23	22

3.4.7.3 Summary scores correlation with EORTC-C30 scores

The patients' summary scores were also correlated with patients' scores in the EORTC-C30 quality of life questionnaire (table 3.4.16). Patient confidence in doctors has a trend to be negatively associated with fatigue ($r = -0.4$; $n = 27$; $p = 0.06$. $r^2 = 0.16$), and with pain ($r = -0.34$; $n = 27$; $p = 0.086$. $r^2 = 0.12$). Increased patient satisfaction with hospital support was associated with better global health ($r = 0.6$; $n = 27$; $p = 0.018$. $r^2 = 0.36$), with better role functioning ($r = 0.43$; $n = 27$; $p = 0.027$. $r^2 = 0.19$), with fewer fatigue symptoms ($r = -0.6$; $n = 27$; $p = 0.001$. $r^2 = 0.36$), with lower pain symptoms ($r = -0.4$; $n = 27$; $p = 0.04$. $r^2 = 0.16$), and with less financial difficulties ($r = -0.5$; $n = 27$; $p = 0.004$. $r^2 = 0.25$). Increased patient satisfaction with social support was associated with better global health ($r = 0.5$; $n = 27$; $p = 0.012$. $r^2 = 0.25$), with lower symptoms of fatigue ($r = -0.4$; $n = 27$; $p = 0.02$. $r^2 = 0.16$), with lower symptoms of dyspnoea ($r = -0.4$; $n = 27$; $p = 0.02$. $r^2 = 0.16$); however, there was a trend for positive association between patients satisfaction with hospital support and role functioning scores ($r = 0.4$; $n = 27$; $p = 0.08$. $r^2 = 0.16$). Better coping was associated with better global health ($r = 0.4$; $n = 27$; $p = 0.05$. $r^2 = 0.16$), with less financial difficulties ($r = -0.4$; $n = 27$; $p = 0.03$. $r^2 = 0.16$); however, there was a negative trend for patient coping attitude with fatigue ($r = -0.4$; $n = 27$; $p = 0.053$. $r^2 = 0.16$), and with pain symptom ($r = -0.4$; $n = 27$; $p = 0.06$. $r^2 = 0.16$). Better patients' perception of their body image were associated with better global health ($r = 0.4$; $n = 27$; $p = 0.025$. $r^2 = 0.16$), with higher physical functioning ($r = 0.5$; $n = 27$; $p = 0.014$. $r^2 = 0.25$), with higher role functioning ($r = 0.5$; $n = 27$; $p = 0.017$. $r^2 = 0.25$), with increased social functioning ($r = 0.43$; $n = 26$; $p = 0.027$. $r^2 = 0.19$), with lower fatigue symptoms ($r = -0.6$; $n = 27$; $p = 0.003$. $r^2 = 0.36$), and with less financial difficulties ($r = -0.6$; $n = 27$; $p = 0.003$. $r^2 = 0.36$). Fatigue symptoms had a trend for negative association with patient satisfaction

with nutritional support (r = -0.4; n = 27; p = 0.07. r^2 = 0.16), and with patient satisfaction with functioning and disability (r = -0.4; n = 24; p = 0.09. r^2 = 0.16).

Table 3.4.16: EORTC-C30 scores correlation with patients' summary scores

		GH	PF2	RF2	SF	FA	NV	PA	DY	FI
Doctors support	r	.131	.064	-.054	-.104	-.364	.166	-.336	-.101	-.096
	Sig.	.515	.752	.790	.615	.062	.419	.086	.618	.634
	N	27	27	27	26	27	26	27	27	27
Hospital support	r	.450	.300	.426	.264	-.618	-.233	-.393	-.315	-.535
	Sig.	.018	.129	.027	.192	.001	.251	.043	.110	.004
	N	27	27	27	26	27	26	27	27	27
Social support	r	.477	.124	.345	.152	-.444	-.407	-.181	-.443	-.052
	Sig.	.012	.539	.078	.459	.020	.039	.365	.021	.798
	N	27	27	27	26	27	26	27	27	27
Coping	r	.388	.255	.264	.145	-.377	-.053	-.361	-.245	-.416
	Sig.	.046	.199	.184	.479	.053	.796	.064	.218	.031
	N	27	27	27	26	27	26	27	27	27
Body image	r	.431	.465	.455	.433	-.547	-.112	-.239	-.199	-.557
	Sig.	.025	.014	.017	.027	.003	.585	.230	.320	.003
	N	27	27	27	26	27	26	27	27	27
Nutritional support	r	.308	.291	.318	.228	-.351	-.071	-.228	-.188	-.160
	Sig.	.118	.141	.106	.263	.072	.731	.253	.349	.424
	N	27	27	27	26	27	26	27	27	27
Functioning /Disability	r	.296	.235	.157	.051	-.351	.066	-.138	-.117	-.165
	Sig.	.160	.269	.464	.816	.093	.764	.519	.585	.441
	N	24	24	24	23	24	23	24	24	24

3.4.7.4 Summary scores correlation with EORTC-H&N35 scores

The patients' summary scores were also correlated with patients' scores in the EORTC-H&N35 quality of life questionnaire (table 3.4.17). Increased patient satisfaction with hospital services and support was associated with lower swallowing problems ($r = -0.4$; $n = 27$; $p = 0.02$. $r^2 = 0.16$), with less trouble with social contact ($r = -0.4$; $n = 26$; $p = 0.02$. $r^2 = 0.16$); however, there was only a trend for negative association between patient satisfaction with hospital support and speech problems ($r = -0.34$; $n = 26$; $p = 0.09$. $r^2 = 0.12$) and with problems with sexual activity ($r = -0.4$; $n = 21$; $p = 0.098$. $r^2 = 0.16$). Increased patient satisfaction with social support was associated with lower trouble with social eating ($r = -0.5$; $n = 25$; $p = 0.02$. $r^2 = 0.25$), and with less symptoms of feeling ill ($r = -0.5$; $n = 27$; $p = 0.01$. $r^2 = 0.25$); however, there was a negative trend for association between patient satisfaction with social support and speech problems ($r = -0.4$; $n = 26$; $p = 0.066$. $r^2 = 0.16$). Better patient coping was associated with less problems with mouth opining ($r = -0.4$; $n = 26$; $p = 0.04$. $r^2 = 0.16$). Increased patient satisfaction with body image was associated with less problems with speech ($r = -0.4$; $n = 26$; $p = 0.03$. $r^2 = 0.16$), with less troubles with social contact ($r = -0.5$; $n = 26$; $p = 0.02$. $r^2 = 0.25$), with less problems with sexual activity ($r = -0.4$; $n = 21$; $p = 0.04$. $r^2 = 0.16$), and with less problems with mouth opining ($r = -0.4$; $n = 26$; $p = 0.03$. $r^2 = 0.16$); however, there was a trend for negative association between patient satisfaction with body image and swallowing problems ($r = -0.3$; $n = 27$; $p = 0.097$. $r^2 = 0.09$). Also, there was a trend for negative association between patient satisfaction with nutritional support and trouble with social eating ($r = -0.4$; $n = 25$; $p = 0.075$. $r^2 = 0.16$).

Table 3.4.17: EORTC-H&N35 scores correlation with patients' summary scores

		SW	SP	SO	SC	SX	OM	FI
Doctors support	r	-.130	.071	-.004	.059	-.285	-.152	-.066
	Sig.	.519	.731	.986	.773	.210	.457	.743
	N	27	26	25	26	21	26	27
Hospital support	r	-.434	-.341	-.314	-.441	-.371	-.272	-.283
	Sig.	.024	.089	.127	.024	.098	.179	.153
	N	27	26	25	26	21	26	27
Social support	r	-.235	-.365	-.460	-.246	-.020	.206	-.489
	Sig.	.237	.066	.021	.227	.930	.314	.010
	N	27	26	25	26	21	26	27
Coping	r	-.117	-.175	-.100	-.192	-.135	-.404	-.209
	Sig.	.560	.391	.635	.347	.558	.041	.295
	N	27	26	25	26	21	26	27
Body image	r	-.326	-.417	-.278	-.446	-.444	-.432	-.178
	Sig.	.097	.034	.179	.022	.044	.028	.376
	N	27	26	25	26	21	26	27
Nutritional support	r	-.190	-.245	-.362	-.162	-.133	-.247	-.197
	Sig.	.342	.227	.075	.429	.564	.223	.325
	N	27	26	25	26	21	26	27

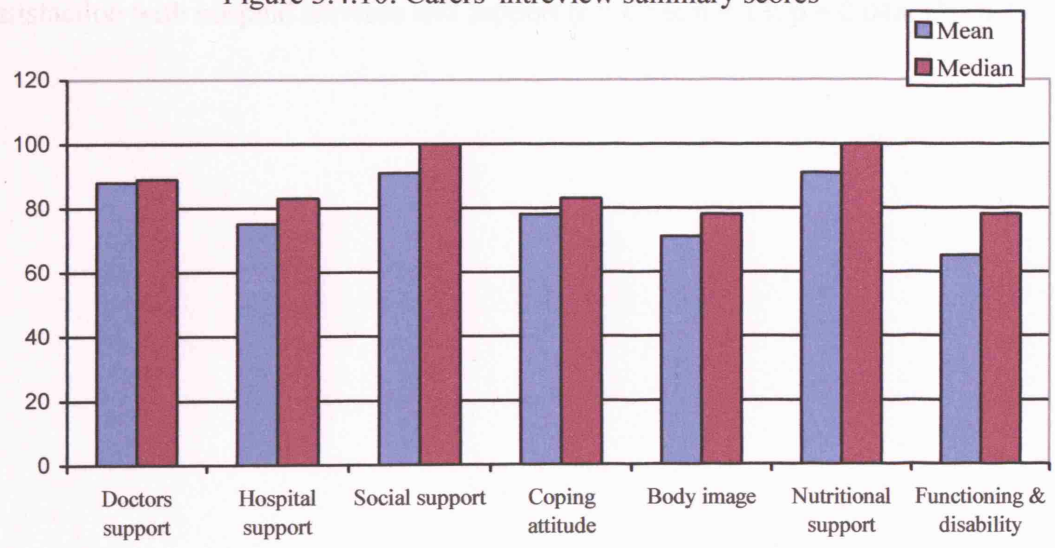
3.4.8 Care-giver interview summary

Care-giver scores from the interview questions are summarized under major the same 7 domains (table 3.4.1) used for patients, and a summary score produced (table 3.4.18).

Table 3.4.18: Summary of care-giver psychosocial support scores

Psychosocial support domains	median	mean
Doctors support	89	88
Hospital support	83	75
Social support	100	91
Coping	83	78
Body image	78	71
Nutritional support	100	91
Functioning & Disability	78	65

Figure 3.4.10: Carers' intreview summary scores



Care-giver summary scores were correlated to patient summary scores (table 3.4.19). There were associations between increased patient satisfaction with doctors'

support and increased care-giver satisfaction with hospital support and services ($r = 0.57$; $n = 13$; $p = 0.04$. $r^2 = 0.33$), with increased care-giver satisfaction with social support ($r = 0.57$; $n = 13$; $p = 0.04$. $r^2 = 0.11$), and with increased care-giver satisfaction with body image ($r = 0.57$; $n = 13$; $p = 0.04$. $r^2 = 0.11$), but a only a trend for association with care-giver satisfaction with nutritional support ($r = 0.54$; $n = 12$; $p = 0.068$. $r^2 = 0.29$). There was a trend also for increased patient satisfaction with hospital services and increased care-giver with hospital services ($r = 0.52$; $n = 13$; $p = 0.07$. $r^2 = 0.27$). There were associations between increased patient satisfaction with social support and increased care-giver satisfaction with social support($r = 0.66$; $n = 13$; $p = 0.014$. $r^2 = 0.44$), and increased care-giver satisfaction with body image ($r = 0.56$; $n = 13$; $p = 0.046$. $r^2 = 0.314$), but a trend for association with care-giver satisfaction with nutritional support ($r = 0.56$; $n = 12$; $p = 0.058$. $r^2 = 0.314$). Increased patient coping attitude associated with increased care-giver satisfaction with social support ($r = 0.58$; $n = 13$; $p = 0.038$. $r^2 = 0.34$). Also, increased patient satisfaction with functioning and disability associated with increased care-giver satisfaction with hospital services and support ($r = 0.56$; $n = 13$; $p = 0.048$. $r^2 = 0.31$).

Table 3.4.19: Association between patients and care-giver in summary scores

		Hospital support (carer)	Social support (carer)	Body image (carer)	Nutritional support (carer)
Doctors support (patient)	R	.573	.568	.567	.542
	Sig.	.041	.043	.043	.068
	N	13	13	13	12
Hospital support (patient)	R	.516	.168	.230	.191
	Sig.	.071	.583	.450	.551
	N	13	13	13	12
Social support (patient)	R	.460	.660	.561	.560
	Sig.	.114	.014	.046	.058
	N	13	13	13	12
Coping (patient)	R	.430	.578	.405	.339
	Sig.	.143	.038	.170	.281
	N	13	13	13	12
Functioning & Disability (patient)	R	.557	.175	.167	.193
	Sig.	.048	.568	.586	.548
	N	13	13	13	12

3.5. Discussion:

3.5.1 Patients' characteristics

The aim of this study was to describe patients' attitude to services provided and correlate it to their HRQOL data. The design of the study is appropriate for understanding complex subjects such as psychosocial support and provides flexibility and freedom to patients in their reply to interviewer questions. The questions used during the interview were selected from questionnaires developed for patients' information needs; the questions were checked for clarity and appropriateness after piloting it on a few patients and changed accordingly.

There were 40 patients interviewed in this study and the mean age was 60 years (SD12) which is considered within normal range for head and neck cancer patients; also, the male: female distribution was 1.7:1 and there was more married (couple) than single (widow) patients, and more unemployed than employed patients which is considered within normal variation of this population. In regards to the level of patients' education one needs to consider that in this sample of patients there was more patients with college / university degree (double) than patients in other levels; and more patients rated themselves with average income level. The majority of the patient did not or stopped consuming alcohol and/or smoke abuse; nonetheless, some continued doing so.

It is notable that in this sample of patients there is a sizable number of patients with recurrent tumours (9-patients), and under representation of patients at preoperative stage (only 2-patients), as well as a small number of patient with segmental bone resection (6-patients) which may reduce the effect of significant facial deformity.

3.5.2 Patients' HADS scores

The HADS scores were used either in the raw format when using correlation analysis or dichotomised around 7, the way used previously (chapter 2) for screening patients for caseness of anxiety or depression. Generally the level of anxiety and depression in this sample of patients was low; these findings coincide with previous findings (chapter 2) of low level of anxiety and depression in head and neck cancer population in general.

However, it is notable that patients at the 4-12 months period have high level of anxiety scores compared to the others in the postoperative stage; also, depression scores were highest in this group of patient. This is different from the findings in the previous chapter where anxiety level peaked during the 0-3 months postoperatively and gradually reduced thereafter. This may be explained by the inclusion of patients with recurrent tumours or the inclusion of head and neck cancer patients under the care of other consultants. These patients may have low level of anxiety at 0-3months period or high anxiety level at 3-12months period. The percentage of patients with anxiety level above 7 was still high relatively at the period >12months similar to finding in the previous chapter.

3.5.3 Patients' Interview

Patients interviewed in this study showed a high level of satisfaction with services and psychosocial support provided; the support was categorized into support from doctors, support from the hospital, social support, coping support, nutritional support, functional/disability support, and support for body image changes. The results from the previous chapter indicate that patients HRQOL improved with time after surgery and approach the preoperative levels after one year; nonetheless, patients continue to suffer from long term side effects such as fatigue, swallowing difficulties, mouth opening, dry

mouth, and sticky saliva problems which may account for the small increase of depression scores in the HADS with time (Nordgren et al. 2003).

Doctor-patient communication and information are an important factor in patient's perception of doctors' psychosocial support (Evans et al. 2003, Fallowfield et al. 1999, Haggmark et al. 2001, Ong et al. 2000, Rankin et al. 2000, Whelan et al. 1997). Patients in this study were highly satisfied with doctors' support provided; this can be due to genuine feelings of autonomy and individuality with doctors during the consultation, or because patient feel vulnerable and see doctors as safe figures to be attached to since the doctor's skills and positive attitude were considered by patients to be the most hope giving (Hagerty et al. 2005, Pileggi et al. 2004). Also, it is possible that the realistic hope-giving attitude of the doctors did help the patients to build some kind of relationship with doctors, which was welcomed by many patients (Hagerty et al. 2005, von Plessen et al. 2005). It was noted that in this group of patients many were not given different choices in treatment; nonetheless, they were given the time to discuss the treatment option thoroughly before starting it. This may indicate that patients want their rights to be well informed and involved in the consultation process and use this information for various aspects of care which may or may not include decisions for treatment (Beaver et al. 2005, Hagerty et al. 2005).

Patients' perception of doctors' support was positively improved with increasing time after surgery and with better psychological functioning; and negatively associated with patients feeling of fatigue, pain and anxiety. It is also noted that confidence in doctors was more in patients who underwent complicated surgical procedures such as vascular-flap surgery and in patients with low education level. This may indicate that patients have less ability to interpret information provided or use hope-seeking behavior for support from

doctors which may negatively affect patient information seeking behavior (Brundage et al. 2005, Leydon et al. 2000, Pileggi et al. 2004).

Satisfaction with information remain a challenge in cancer patients; in this study many patients were confused, overwhelmed and dissatisfied with clarity of information or the way it was delivered; this was mainly due to given a lot of information all at once, or by someone different from the doctor on-charge (van Vliet et al. 2004), which could add to the patient suffering. On the contrary, there were many others who criticized doctors for being concerned more about the long or important side effects but not the short or trivial ones. In addition, there were patients who doubted their ability to take the correct decision or believe there wasn't much time to think, therefore, they put extra trust and hope in doctors, and leave the decisions in treatment to them. Other patients chose to ignore treatment side effects and decided to deal with it when it happened, or did not want a bulk of information at that point. Nonetheless, all patients found side effects shocking, distressing and confusing when it happened even when they knew about it.

Supporting patients with information about several services the hospital can provide and how to benefit it improved their satisfaction with the treatment provided and reduced much of their fear and anxiety feelings (Evans et al. 2003, Gallant et al. 2003, Gourdji et al. 2003, Thewes et al. 2004). In this study, patients' satisfaction with hospital support increased with time after treatment and with increase in general health perception, physical functioning, social functioning, psychological indices; and decrease in problems of pain, finance, weakness and eating indices.

It is important for patient to develop a relationship with key individuals during illness; however, paternalistic patient-doctor relationship may act as a barrier for patient

involvement in service development (Evans et al. 2003). Furthermore, patients' perception of care was negatively affected by the limitation of hospital resources such as transport and car parking (Fincham et al. 2005). Nurses play a significant role in the support provided to cancer patients especially the clinical nurse specialist; and patients in this study were highly satisfied with nurses' support and services. Patients found hospital staff and local (community) counselors supportive in managing distressing feelings. However, it was noted that patients managed their distress in different ways; some looked for support from people (family, friends, doctors, nurses, support group, self) and some dealt with it alone (e.g. prayers, meditation, excessive house work or alcohol drinking), while others (especially patients with recurrence) learned to live with cancer.

The good nursing support was dented due to many reasons such as staff shortages that led to shortness or inadequacy in services provided to some patients, not providing patients with other sources for information like the internet, providing patients with information about hospital services late in recovery period. Also, nurses' support for managing distressing feelings especially at critical time like during or immediately after operation was criticized by many patients who wished to discuss the issue with a person who had a background in psychological support.

Information and auxiliary sources for it such as the internet or second opinion increased patients satisfaction, and valued by both cancer patients and care-givers (Kirk et al. 2004, Little et al. 2004, Newell et al. 2004). Dissatisfaction with information in cancer patients have been reported previously, and for many different reasons (Gesell et al. 2004, Gourdji et al. 2003, von Plessen et al. 2005); moreover, cancer patients have endless needs for information at different times and with different styles (Evans et al. 2003, Thewes et al.

2004). Therefore, in busy units adequate staffing as recommended in the NICE guidelines (2004) is essential for continuity and coherence of quality services (NHS 2004).

The majority of the patients felt the respect at the clinic was mutual with hospital staff. The long waiting time in small inconvenient clinical space and difference in both waiting and consultation time between patients without proper explanation gave some patients feeling of disrespect. A few measures to improve this have been suggested like simplifying the care process, having a network computer and printer -for retrieving laboratory results and radiographs-, having computerized patient data in the clinic, reviewing appointment scheduling system, and increasing team members' motivation and awareness (Gourdji et al. 2003, Rondeau 1998, von Plessen et al. 2005); some of these have already been implemented. Nonetheless, patients were very tolerant and understanding for the pressure load on doctors.

Social deprivation and diminished self impose significant threats to cancer patients (Moore et al. 2004b, Whelan et al. 1997). Family members/duties and friends played a significant role in providing patients with social support and a sense of control in life. This was demonstrated in the positive attitude of many patients who still enjoy going out socially with friends and relatives and patient appreciation to family members support at home. Social support (especially from family or relatives) was positively associated with QOL in caner patients (Han et al. 2005, Parker et al. 2003). This study found that patients' perception of good social support was associated with global health perception, improvement in psychological, tiredness, and eating indices. Also, patients' perception of good social support (especially in people with higher education level) increased with time and in patients with lower depression scores in the HADS; this may shed light on the finding of increased depression scores in head and neck cancer patients with time.

Spirituality and religion is a significant aspect in peoples' life from different ethnic background and plays a role in coping with crises events such as cancer (Burton 1998, True et al. 2005). Spiritual healing, meditation especially prayers are some complementary therapies that are frequently used by cancer patients; and although the evidence is inconclusive if these methods contribute to psychological healing, there is a growing evidence indicating a positive emotional outcome (Taylor 2005). Patients in this study were highly satisfied in their spiritual needs; some were not religious and did not feel the need for a spiritual advisor, while others believe in holistic practices and performed homeopathic meditation or prayers or see one of their friends/relatives as a spiritual advisor. It is noted that few patients were limited in their social activity; this was due to many reasons such as living alone with no close family or friend, physical problems like mouth burning sensation and difficulty in eating, and mental problems like worries and distress. These patients are at risk of developing psychological problems such as social isolation and anxiety (Brunello et al. 2000, Wittchen 2000).

Support from people with a similar condition is part of the social support provided to cancer patients (Taylor et al. 2004a). Patients may develop coping and adaptive mechanism to consequences of cancer and its treatment by expressing emotion to others with a similar condition or by participating in educational behavior activities. Other benefits of support group include reducing the sense of helplessness and fear experienced by patients, encouraging patients to improve their communication skills with others, promoting the relief of cancer related distress, improving psychological wellbeing, providing practical assistance, emotional support, sense of belonging and realistic information relating to the course of the illness (Docherty 2004, Haggmark et al. 2001, Penson et al. 2004, Weis 2003).

In this study the role of support group was recognized only by few patients. Some patients knew about the benefits of meeting others with a similar condition and many others did not, but nurses failed to promote these benefits between patients. The use of support group was lower in male patients (could be due to shyness), in patients at time of treatment or shortly thereafter, and in patients with increased fatigue and mouth opening problems. Other patients did not think they would benefit from talking to others with a similar condition or preferred not to speak about personal matters. Further research is needed in the ways to overcome such limitations.

Cancer patients recognized that maintaining a sense of control, family support and maintaining hope are important factors for coping (Bulsara et al. 2004). Many patients were optimistic about the future; others were realistic and some "live - enjoy" their day when possible. Some patients got a lot of support from their prayers and some were happy to be alive as long as the kids' future is secured. Negative emotion-focused coping was reported to be negatively associate with QOL in head and neck cancer patients (He et al. 2005). In this study, few patients averaged their outcast for the future and related that to their recovery from treatment, probably because "the side effects of treatment are constant remainder of cancer" as patient said. These patients are at risk of being fatalistic about doctors' ability to cure them as they may underreport their experience due to fear and experience greater psychological morbidity (Moore et al. 2004a).

Few patients were experiencing the change after treatment and find it difficult to cope with house/kids or office work demands, or in constant worry; therefore do not enjoy their personal time. This is part of the fatigue symptoms commonly experienced in cancer patients (Lindqvist et al. 2004). Cancer related fatigue can be due to treatment (e.g. radio. or chemotherapy), or physiological (e.g. reduced metabolism), nutritional, psychological

(e.g. depression) factors, and affect QOL negatively (Ahlberg et al. 2004, Lindqvist et al. 2004, Molassiotis et al. 2004). Fatigue is related to other symptoms assessed in HRQOL instrument such as feeling ill and energy/vitality that collectively indicate patient feeling of weakness; and these symptoms were found to be negatively correlated to patients' perception of doctors' support, hospital support, social support, coping support, and support for image changes.

Majority of the patients were satisfied with support provided for their body image changes. Many reasons were identified for the high satisfaction score:

- Patients needed little support as they do not feel there is a dramatic of change in their look
- Patients used the support provided by the hospital staff, local counsellors and their family/friends; which was also helpful in maintaining senses of self confidence
- Patients adapted to changes in body image in long survivors
- Patients had no interest in going out socially.
- Patients felt lucky for being alive, and comfortable for the way they look for their age.
- Many patients felt independent and lived with or without relatives living nearby and continued to go out socially with friends and relatives.

Head and neck cancer patients are at risk of developing social and psychological problems due to body image changes (Dropkin 2001, Rumsey et al. 2004). This study found that increased patients satisfaction with support for body image changes was

correlated with improved perception of general health, physical functioning, social functioning, speech and financial problems, psychological, weakness and eating indices. This correlation to most of the HRQOL aspects indicates that the approach to treatment of body image changes needs to be comprehensive (Stewart 2004). There were few patients who were worried and concerned about their body image; others felt very limited socially as a result of distress from the disease or because of the changes that occurred after treatment which reflected on their body image as a whole. Support for coping with body image changes was criticized by these patients who wished to discuss the issue with a professional person.

Head and neck cancer patients are at risk of developing functional disability as result of treatment; and several reasons have been identified such as pain, depression, shoulder movement and financial difficulties (van Wilgen et al. 2004, Whelan et al. 1997). In this study, patients' satisfaction with functional disability support was more in patients with higher level of education; however, negatively correlated with financial problems, and psychological and eating indices. Functional disability is becoming increasingly more recognizable as oral and pharyngeal cancer is increasing in pre-retirement age population (Hindle et al. 1996, La Vecchia et al. 1997, Mackenzie et al. 2000). The hospital does provide financial advice services and support when possible and around 50% of the patients found the financial advices or supports provided helpful or not needed; however, many others criticized the financial support provided being not enough and wished that they had some help or at least advice on financial matters as they find life becoming more difficult with time. Many reasons have been identified for cancer patients not to claim financial benefits such as not knowing their rights to benefits, or finding claim forms complicated or

having a stigma in claiming financial help or advice was provided at the wrong time (Chapple et al. 2004).

Malnutrition affects cancer patients' quality of life, complication and prognosis, especially in elderly patients (Genden et al. 2005, Grobbelaar et al. 2004); and head and neck cancer patients are at risk of developing short and long term eating problems that negatively affect patient functional ability (Hammerlid et al. 2001a). Patients' satisfaction with nutritional support was high in this study; it increased with increased physical functioning and with decreased psychological indices. Research showed that quality of life issues were more related to patient's dental status rather than limitation of mouth opining (Duke et al. 2005). Eating problems in head and neck cancer patients remain as significant problems even in long term survivors (Grobbelaar et al. 2004); patients and their caregivers in this study criticized the dieticians for not working with patients to customize recipes or ways of cooking to suite individual patients.

The caregivers at home play a great role in the caring process, and patient closeness to relatives is important for creating sense of living and safety in difficult situation (Appelin et al. 2004). Cancer patients consider family members as important additional coping resource, providing social and emotional support (Miyata et al. 2004, Saares et al. 2005). However, caregivers psychological and social functioning will be affected by caring for cancer patients; therefore, information support to care-giver for coping and self care should be considered in the overall care for cancer patients (Appelin et al. 2004, Northouse et al. 2002). Involving care-giver in the treatment of head and neck cancer resulted in significant patient's mental health communication improvement (McLane et al. 2003, Northouse et al. 2005). Patients perception of psychosocial support provided was satisfactory in most of the themes recognized. This correlated well with patients' perception of the psychosocial

support provided except for doctors' support, disability support and support for changes in body image.

3.5.4 Patients and caregivers suggestions:

There were few suggestions from patients and carers on how to improve services provided in the unit. It is summarized into categories as follow:

Patient opinion on unit services

Patients expressed their satisfaction with the information and services provided in the unit and the easy access to doctors and nurses, and the concern from staff in the unit and wished for continuity of the services at the same level. Also, caregivers complemented the receptionist particularly in mailing appointments on short notice.

Clinical services

Patients and caregivers suggested the followings for improving the clinical services provided at the unit:

- Allocating realistic time slots for patients, giving a reason for delays and providing more comfortable seats and air condition in the waiting area.
- Providing dental care at the unit for oral and pharyngeal cancer patients before and after treatment.
- Keeping close follow-up appointments for surveillance as recurrence is a constant source of worry, this may give patients safer and less anxious feelings.

- Old and disabled cancer patients and those living far from the treating hospital find it difficult to travel long distances for review appointment, it is preferable that one of the specialist visit the local medical practitioner clinic and arrange to see all people needing to be reviewed in the local area.

- All patients should have a quick access to a diet specialist.

- More work needs to be done to improve hospital food, with aims of restoring patient's body energy and physical ability; diet services and advices need improvement.

- Contact numbers and names of consultant in the unit dealing with mouth cancer and pre-cancer should be available to each patient, may be a diary for patient with all contact numbers of people involved in patient management (e.g. relatives, GP, GDP, Surgeons.....etc).

- Patients should be provided with a phone contact number to ask questions after being informed bad news.

- The clinic needs a close-by car park as many patients are old and/or disabled.

- The need for readable maps for the different hospital departments.

- Carers suggested the use of a scope for oral examination, rather than many people "peering" into patient mouth.

- Wish to have a local cancer support hotline by the UCLH, similar to the national one.

Counseling services

Patients believe that recurrence is always a source of worry to cancer patients and long-term side effects of treatment are constant reminder of the disease and possibility of recurrence. Therefore, professionals need to send a message stressing that cancer is not a terminal disease and that recurrence is part of cancer; focusing more on teaching patients how to live with it, and how to deal with worries such as securing the family future. Other important issues that may cause anxiety to patients and that need to be addressed in the management of cancer patient are finance, re-socialization (social isolation) and support from family.

Patients and caregivers recommended paying more attention to emotional wellbeing similar to the attention given to physical wellbeing. They recommend in-house psychologist or professional counselor (the CNS at the moment); and wished for counseling services to extend to family members as well.

Patient Education

Patients and caregivers wished to have more information with better demonstration (illustrations when possible) about treatment procedure (including radiotherapy) and treatment side effects and about pain management during treatment before starting any treatment and clear instructions on how to maintaining proper mouth hygiene. Also, one patient revealed his need for information about common mouth changes that predispose cancer.

Patients and caregivers wished to be offered alternative source of information like a second opinion, or be directed to credible internet sites or patients. Also, patients wished

for information booklet about new treatment applied in the unit to give their doctors abroad to familiarize them about treatment they have received. Caregivers also wished to know about support that can be provided to patient at home.

Patients wished surgeons would give better or clearer description of what will happen in theater and during recovery and the extent of deformity and limitation after surgery, possible side effects and its management.

Confidence in doctors

Disappointing news such as inconsistent pathology reports or news of incomplete excision are depressing and damaging to the patients trust in the treating consultant, which is an important factor for patient sense of control and not being depressed.

Professionals' education

Patients suggested that doctors should properly assess the patients' education level as further discussion and management will depend on patient ability to understand and communicate. This will affect the patient short and long term management. Moreover, the frequent uses of medical terminologies (such as maxillofacial, cancer, head and neck surgeons) are overwhelming and make patients tense coming to a place like this. One patient stated that "he only met the consultant before the surgery and thinks this is quite terrible; and would have preferred not meeting him and would have liked one of the registrars to introduce themselves as being in charge of his care".

SHOs and nurses need to know more about the patient psychological situation and needs in the intensive treatment unit (ITU). Nightmares in ITU and the 1st night back in the ward are not uncommon and it was very frightening; therefore, patients must be informed

about it. Also, doctors and supporting staff need to know the value of high morals for cancer patients and that the after-care provided to patients is essential in rehabilitation process. The value of positive, warm, humanitarian attitude of doctors and nurses at early stage after operation was demonstrated in one patient saying that doctors words "how wonderful to see you walking, you look good today" boost her morals in the early postoperative days and encouraged her to walk sooner than she expected. In addition, there is a need to improve doctors knowledge about latest/new treatment applied in the unit (such as PDT), as patient find it frustrating when the doctor on charge do not know much about treatment provided in the hospital.

Communication

Patients and caregivers recommend that doctors and nurses make patients aware of the benefits of talking to other patients with a similar condition and encourage them to communicate. Possibly by inviting patients to support groups in the unit or providing them with a list of patients' names and phone numbers with similar condition who are willing to talk. Caregivers wished to attend support group for patients' relatives with or without patients.

Patients also suggested that doctors and nurses encouraged patients to ask questions and communicate better with the management team. Caregivers also wished for opportunities to ask doctors questions when patients were not around.

One patient suggest that "doctors/nurses need to involve the patient in recognizing their own problems (such as using video-taped interview) and finding ways to overcome it by setting targets and working hard to reach them, increase patients confidence in their ability to survive and rehabilitate to preoperative level, set plans, help patient attain goals

set in the plan, expect some failure but sure outcome is worth it". Communication is not only for patients but also for members of the multidisciplinary team who need to be more organized and better communicated.

Caregivers suggested that bad news should be delivered only by the treating (or familiar) consultant; also that consultants needed to break down appointments, one for diagnosis and one for treatment plan, as this would give more time for questioning.

Financial support

Patient and caregivers would have liked more information about financial support / benefits available to patients and their families while in hospital and upon returning home.

Transport problems

Patients who travel long distances for review appointment wished if their local doctors has the knowledge and experience to do the follow ups, or by creating a weekly district consulting clinic.

3.6 Study limitation

This study has some limitations which need to be considered. The number of patients is small and this limits generalization of the findings. Patients at preoperative stage or receiving palliative treatment are under represented in this study; therefore, their influence on the results is weak. One of the inclusion criteria was ability of the patients to speak and understand English; this resulted in underreporting of significant psychosocial problems in the non-English speaking community affected by this language barrier. Also, the interview was carried out in the hospital or the clinic on selected patients who agreed to participate after seeing the doctors, and only few care-givers participated because of refusal or not answering the phone at home or not being present (patient lives alone); this can be improved in the future by doing the interview in a more relaxed environment such as the patient's home hence the chances of involving care-givers would be more. Moreover, Participants interviewed were from different management intervals and there is a possibility that they may have emphasized certain aspect of their experience rather than its entirety. The results of this study may lack reliability and validity because of informal sampling technique, individual biases of the interviewer, and difficulties in recording, coding, and analyzing the data. However, in an attempt to improve the validity of the finding two methods have been used (triangulation), interview and Likert scale. One other method that could be used in the future is involving a second researcher in the interview to double check the findings (Mays et al. 2000).

The interview was categorized into 7 themes and results need to be considered under sub-themes involved in each. Also, indices used here are used for summarizing multiple HRQOL domains or symptoms from the SF-36, EORTC-C30, and EORTC-H&N35 questionnaires. Psychological indices refer to mental health, cognitive

functioning, limitations due to emotional problems, and role emotional. Tiredness indices refer to fatigue, feeling ill and levels of energy/vitality. Eating indices refer to swallowing problems, nausea/vomiting, troubles with social eating, mouth opening problems, and appetite loss.

Chapter 4

4. Conclusion

The study found that the multidisciplinary team approach was satisfying the patients' need for informational support about their disease management. Important influencing factors in patients satisfaction were the diagnosis of cancer and the psychosocial support system provided at the maxillofacial unit. In future, applying this approach to educate patients attending the oral medicine clinic will verify its validity. The limitation to this approach is that it relies on the staff attitude, available time to talk through issues of concern to the patient; availability of information when needed, appropriate training of all the staff and a strict protocol of care applied.

Patients recognised Consultants as the best source of information. A few patients wished their GP or dentists (GDP) were more involved in their management, this highlights the need for continuous professionals' education about oral diseases and emphasises the importance of communication between the treating specialist and GP or GDP.

Written information is an effective method of supplementing verbal information and patients expressed a strong preference for written information. The written format is a popular, practical, cheap and effective educational method; however, it does have limitations and should only be used as a supplement but not a substitute for good interpersonal skills of the health care provider. The use of other forms of educational materials can supplement the written format in certain groups; however, the advantages should at least match the effort and money needed for its development and application. It is interesting that modern technology for information delivery such as Internet and CD-Rom were not popular. This may reflect the age and attitude of the study population, but may also change with time.

Anxiety and depression are common in oral and pharyngeal cancer patients. Anxiety scores that were found to be high at the preoperative stage gradually improved with time after treatment while depression scores slightly and gradually increased. A similar pattern was reported in previous studies, although the percentages of people with caseness for anxiety in this study were higher before and after treatment than those reports. This study helps in alerting the surgeons about the patients' high anxiety state at the preoperative stage and stresses the need for continuous assessment of patients for anxiety after surgery. It also calls for further investigations into the role of information in the control of cancer patient's anxiety and depression.

Patients with head and neck cancer often experience debilitating speech, eating, and respiratory problems as well as the psychological effects of loss of function and change in body image. Increasing head and neck cancer rates is of concern in the pre-retirement population as patients often become unemployed as a result of their disease process, adding a financial burden to their already stressful lives. Patients with head and neck cancer who have undergone neck dissection or have high pain scores are at an increased risk for disability from the cancer or its treatment.

This study supports the use of the HADS, SF-36, and EORTC-C30 and EORTC H&N35 questionnaires for the assessment of patients' quality of life in the unit. There was a strong association between the eight domains of the SF-36 and their corresponding domains in the EORTC-C30, and the EORTC H&N35 was more sensitive in measuring the differences in the patients' symptoms at different stages. Preoperative predictors were better correlated with the SF-36 functional/symptoms scores while the postoperative predictors correlated better with the EORTC H&N35 symptoms/ items scores. Therefore, it is preferable to use both systems for the assessment of patients' HRQOL.

Short and simple questionnaires such as the HADS are easy to administer in the clinic regularly. The scale screens patients for anxiety and depression and monitors the progress, as will as predicting changes in other aspects of quality of life. The HADS-anxiety demonstrated a moderate to strong association with HRQOL domains in the SF-36, most of the EORTC-C30 and H&N35; and equations have been postulated accordingly. Regular measurement of anxiety in the HADS will give a prediction to the HRQOL scores in other questionnaires. The results can be compared with the actual values of the domains measured in the specific questionnaire every few months. This is useful when closely monitoring patients and predicting the scores of dropout patients.

This research suggests that interventions that can effectively improve patients' perception of psychosocial support will improve patients HRQOL. Moreover, despite the problematic methodological issues, the qualitative approach combined with quantitative measures of HRQOL increase patients participation in their strategic health planning; and gives better evaluation of patients' perception of services provided via identifying shortages such as financial and nutritional support. Thus, further research with a more heterogeneous sample (stage of treatment and ethnic background) would enhance the utility of this study.

The application of QOL assessment in the clinical setting is difficult and laborious; therefore, extra measures are necessary to facilitate its future application. In any future study, if patient's quality of life is to be measured and monitored the clinical professional and non professional staff should be aware of the research aims, significance, and methods and should cooperate where possible. A "clinic-based person" should be responsible for:

- Answering all enquiries from patients, and hospital administration
- Organising the application and follow up of questionnaire

- Collecting and auditing the results, and monitoring progress
- Communicating with other QOL researcher fellows
- Compliance is better when questionnaires are completed on site, therefore, it would be of great help if a quiet place could be allocated in the unit for this purpose.

Gender and facial disfigurement have great significance in oral and pharyngeal cancer but the relationship to HRQOL outcome is unclear, the two are likely to be correlated and significantly influenced by the individuals coping technique. Social anxiety is an established psychological disease and the influence of facial disfigurement on social phobia (anxiety) has been reported. Oral and pharyngeal cancer patients are facially disfigured after surgery, which may be a problem especially for female patients (Hassanein et al. 2001). Previous studies have reported mixed correlations of facial disfigurement and quality of life domains (Rogers et al. 1998b). The role of social anxiety in head and neck cancer patients, and its influence on patient's quality of life is an interesting direction for future research and may support the addition of facial disfigurement domains to the EORTC-C30 and H&N35 questionnaires.

Data from quality of life research on oral and pharyngeal cancer from European countries could be gathered to give a general description of quality of life changes and influencing factors. This will help in recognising factors that may be utilised to improve outcomes in different units; statistical manipulation of such data in the form of multiple regression analysis may allow the formulation of prediction equations for close monitoring of patients' progress and customise interventions.

References

Aaronson, N. K. 1991, "Methodologic issues in assessing the quality of life of cancer patients", *Cancer*, vol. 67, no. 3 Suppl, pp. 844-850.

Aaronson, N. K., Meyerowitz, B. E., Bard, M., Bloom, J. R., Fawzy, F. I., Feldstein, M., Fink, D., Holland, J. C., Johnson, J. E., Lowman, J. T., & . 1991, "Quality of life research in oncology. Past achievements and future priorities", *Cancer*, vol. 67, no. 3 Suppl, pp. 839-843.

Aarstad, H. J., Aarstad, A. K. H., Birkhaug, E. J., Bru, E., & Olofsson, J. The personality and quality of life in HNSCC patients following treatment. Eur J Cancer 39, 1852-1860. 2003.
Ref Type: Journal (Full)

Adlard, J. W. & Hume, M. J. 2003, "Cancer Knowledge of the General Public in the United Kingdom: Survey in a Primary Care Sitting and Review of the Literature", *Cancer Oncology* no. 15, pp. 174-180.

Ahlberg, K., Ekman, T., Wallgren, A., & Gaston-Johansson, F. Fatigue, psychological distress, coping and quality of life in patients with uterine cancer. J Adv Nurs 45[2], 205-213. 2004.
Ref Type: Journal (Full)

Al-Rizzeh, S., Mazrani, W., Wray, J., Modine, T., Nakamura, K., George, S., Ilsley, C., & Amrani, M. 2004, "The clinical outcome and quality of life following minimally invasive direct coronary artery bypass surgery.", *J Card Surg*, vol. 19, no. 1, pp. 12-16.

Appelin, G. & Bertero, C. Patients' experiences of palliative care in the home. Cancer Nurse 27[1], 65-70. 2004.
Ref Type: Journal (Full)

Babcock, D. & Miller, M. 1994, *Cliant Education: Theory and Practice* Mosby.

Baker, C. A. 1992, "Factors associated with rehabilitation in head and neck cancer", *Cancer Nurse*, vol. 15, pp. 395-400.

Barkhordar, A., Pollard, D., & Hobkirk, J. A. 2000, "A comparison of written and multimedia material for informing patients about dental implants", *Dent.Update.*, vol. 27, no. 2, pp. 80-84.

Barlow, J. & Wright, C. 1998, "Knowledge in patients with rheumatoid arthritis: a longer term follow-up of a randomized controlled study of patient education leaflets.", *British Journal of Rheumatology*, vol. 37, pp. 373-376.

Beaver, K., Susnerwala, S., Tomlinson, M., Witham, G., & Lucker, K. A. Exploring the decision-making preferences of people with colorectal cancer. Health Expectations 8[2], 103-113. 2005.

Ref Type: Journal (Full)

Beck, J. G., Stanley, M. A., & Zebb, B. J. 1996, "Characteristics of generalized anxiety disorder in older adults: a descriptive study", *Behav.Res.Ther.*, vol. 34, no. 3, pp. 225-234.

Berard, R. M. Depression and anxiety in oncology: the psychiatrist's perspective. Journal of Clinical Psychiatry 62[Suppl 8], 58-61. 2001.
Ref Type: Journal (Full)

Bergelt, C. Questionnaires in psycho-oncology research, litrerature and website links for selected instruments. http://www.ipos-society.org . 2005.
Ref Type: Electronic Citation

Bertelsen, A. 1999, "Reflections on the clinical utility of the ICD-10 and DSM-IV classification and their diagnostic criteria", *Australian and New Zealand Journal of Psychiatry*, vol. 33, pp. 166-173.

Bilodeau, B. A. & Denger, L. F. 1996, "Information need, sources of information and decisional roles in women with breast cancer", *Oncol Nurs Forum* no. 23(4), pp. 691-696.

Bjelland, I., Dahl, A. A., Haug, T. T., & Neckelmann, D. The validity of the Hospital Anxiety and Depression Scale, An update literature review. Journal of Psychosomatic Reasearch 52, 69-77. 2002.
Ref Type: Journal (Full)

Bjordal, K., de Graeff, A., Fayers, P. M., Hammerlid, E., van Pottelsberghe, C., Curran, D., Ahlner-Elmqvist, M., Maher, E. J., Meyza, J. W., Bredart, A., Soderholm, A. L., Arraras, J. J., Feine, J. S., Abendstein, H., Morton, R. P., Pignon, T., Huguenin, P., Bottomly, A., & Kaasa, S. 2000, "A 12 country field study of the EORTC QLQ-C30 (version 3.0) and the head and neck cancer specific module (EORTC QLQ-H&N35) in head and neck patients. EORTC Quality of Life Group", *Eur J Cancer*, vol. 36, no. 14, pp. 1796-1807.

Bloom, J. R. 1991, "Quality of life after cancer. A policy perspective", *Cancer*, vol. 67, no. 3 Suppl, pp. 855-859.

Boudioni, M., McPherson, K., Mossman, J., Boulton, M., Jones, A. L., King, J., Wilson, E., & Slevin, M. L. 1999, "An analysis of first-time enquirers to the CancerBACUP information service: variations with cancer site, demographic status and geographical location", *Br.J Cancer*, vol. 79, no. 1, pp. 138-145.

Boundouki, G., Humphris, G., & Field, A. 2004, "Knowledge of oral cancer, distress and screening intentions: longer term effects of patient information leaflet", *Patient Education and Counseling*, vol. 53, pp. 71-77.

Bowling, A. 1995, *Measuring disease* Open university press.

Bradley, P. Editorial: Head and neck cancer, England, UK-action is getting faster, have you not noticed? Br.J Oral Maxillofac.Surg. 2005.
Ref Type: Journal (Full)

Brown, J. T. & Stoudemire, G. A. 1983, "Normal and pathological grief", *JAMA*, vol. 250, no. 3, pp. 378-382.

Brundage, M., Feldman-Stewart, D., Leis, A., Bezjak, A., Denger, L. F., Velji, K., Zetes-Zanatta, L., Tu, D., Ritvo, P., & Pater, J. Communicating quality of life information to cancer patients: a study of six presentation formats. Journal of Clinical Oncology 23[28], 6949-6956. 2005.
Ref Type: Journal (Full)

Brunello, N., Den Boer, J. A., Judd, L. L., Kasper, S., Kelsey, J. E., Lader, M., Lecrubierh, Y., Lepinej, J. P., Lydiard, R. B., Mendlewiczl, J., montgomerym, S. A., Racagnia, G., Steino, M. B., & Wittchen, H. U. 2000, "Social phobia: diagnosis and epidemiology, neurobiology and pharmacology, comorbidity and treatment", *Journal of Affective Disorder*, vol. 60, no. 1, pp. 61-74.

Bulsara, C., Ward, A., & Joske, D. Heamatological cancer patients: achieving a sense of empowerment by use of strategies to control illness. Journal of Clinical Nursing 13[2], 251-258. 2004.
Ref Type: Journal (Full)

Burton, L. A. The spiritual dimension of palliative care. Semin.Oncol.Nurs 14[2], 121-128. 1998.
Ref Type: Journal (Full)

Butow, P., Maclean, M., dunn, S. M., Tattersall, M., & Boyer, M. J. 1997, "The dynamic of change: cancer patients' preference for information, involvement and support", *Ann.Oncol.*, vol. 8, no. 9, pp. 857-863.

Calman, k. & Hine, d. 1995, *Policy framework for commissioning cancer services*, London: Department of Health, London.

Carroll, B. T., Kathol, R. G., Noyes, R. Jr., Wald, T. G., & Clamon, G. H. Screening for depression and anxiety in cancer patients using the Hospital Anxiety and Depression Scale. General Hospital Psychiatry 15[2], 69-74. 1993.
Ref Type: Journal (Full)

Caumo, W., Schmidt, A. P., Schneider, C. N., Bergmann, J., Iwamoto, C. W., Adamatti, L. C., Bandeira, D., & Ferreira, M. B. 2001, "Risk factors for postoperative anxiety in adults", *Anaesthesia*, vol. 56, no. 8, pp. 720-728.

Cawsey, A. J., Webber, B. L., & Jones, R. B. 1997, "Natural language generation in health care", *J Am.Med.Inform.Assoc.*, vol. 4, no. 6, pp. 473-482.

Chalmers, K. I., Luker, K. A., Leinster, S. J., Ellis, I., & Booth, K. 2001, "Information and support needs of women with primary relatives with breast cancer: development of the information and support needs questionnaire", *Journal of Advanced Nursing*, vol. 35, no. 4, pp. 497-507.

Chapple, A., Ziebland, S., McPherson, A., & Summerton, N. Lung cancer patients' perceptions of access of financial benefits: a qualitative study. British Journal of General Practice 54[505], 589-594. 2004.
Ref Type: Journal (Full)

Christensen, H., Jorm, A. F., Mackinnon, A. J., Korten, A. E., Jacomb, P. A., Henderson, A. S., & Rodgers, B. 1999, "Age differences in depression and anxiety symptoms: a structural equation modelling analysis of data from a general population sample", *Psychol.Med.*, vol. 29, no. 2, pp. 325-339.

Chumbley, G., Hall, G., & Salmon, P. 2002, "Patient-controlled analgesia: what information does the patient want?", *Journal of Advanced Nursing*, vol. 39, no. 5, pp. 459-471.

Chung, V., Horowitz, A. M., Canto, M. T., & Siriphant, P. 2000, "Oral cancer educational materials for the general public: 1998", *J Public Health Dent.*, vol. 60, no. 1, pp. 49-52.

Clark, A. 2000, *Resourcing and training head and neck cancer nurse specialist to deliver a social rehabilitation program to patients,* University of London.

Cohen, S., Miller, G. E., & Rabin, B. S. 2001, "Psychological stress and antibody response to immunization: A critical review of the human literature", *Psychosomatich Medicine*, vol. 63, pp. 7-18.

Coulter, A., Entwistle, V., & Gilbert, D. 1998, "Accessibility of patient information," in *Informing Patients, An assessment of the quality of patient information materials*, 2nd edn, King's Fund, pp. 13-14.

Coulter, A., Entwistle, V., & Gilbert, D. 1999, "Sharing decisions with patients: is the information good enough?", *BMJ*, vol. 318, no. 7179, pp. 318-322.

Crawford, P. R. 1994, "The patient's need to know", *J Can.Dent.Assoc.*, vol. 60, no. 6, p. 479.

Dalton, L. & Gartenfeld, E. 1981, "Evaluating printed health information for consumers", *Bull.Med.Libr.Assoc.*, vol. 69, no. 3, pp. 322-324.

De Boer, M. F., McCormick, L. K., Pruyn, J. F., Ryckman, R. M., & van den Borne, B. W. 1999, "Physical and psychosocial correlates of head and neck cancer: a review of the literature", *Otolaryngol.Head Neck Surg.*, vol. 120, no. 3, pp. 427-436.

De Boer, M. F., van den Borne, B. W., Knegt, P. P., Ryckman, R. M., & Verwoerd, C. D. A. 1995, "Rehabilitation outcomes of long-term survivors treated for head and neck cancer", *Head & Neck*, vol. 17, pp. 503-515.

de Graeff, A., de Leeuw, J. R., Ros, W. J., Hordijk, G. J., Blijham, G. H., & Winnubst, J. A. 1999, "A prospective study on quality of life of patients with cancer of the oral cavity or oropharynx treated with surgery with or without radiotherapy", *Oral Oncol.*, vol. 35, no. 1, pp. 27-32.

de Graeff, A., de Leeuw, J. R., Ros, W. J., Hordijk, G. J., Blijham, G. H., & Winnubst, J. A. 2000, "Pretreatment factors predicting quality of life after treatment for head and neck cancer", *Head Neck*, vol. 22, no. 4, pp. 398-407.

de Graeff, A., de Leeuw, J. R., Ros, W. J., Hordijk, G. J., Blijham, G. H., & Winnubst, J. A. 2001, "Sociodemographic factors and quality of life as prognostic indicators in head and neck cancer", *Eur J Cancer*, vol. 37, no. 3, pp. 332-339.

de Groot, K. I., Boeke, S., van den Berge, H. J., Duivenvoorden, H. J., Bonke, B., & Passchier, J. 1997, "The influence of psychological variables on postoperative anxiety and physical complaints in patients undergoing lumbar surgery", *Pain*, vol. 69, no. 1-2, pp. 19-25.

de Haes, J., Curran, D., Young, T., Bottomley, A., Flechtner, H., Aaronson, N., Blazeby, J., Bjordal, K., Brandberg, Y., Greimel, E., Maher, J., Sprangers, M., & Cull, A. 2000, "Quality of life evaluation in oncological clinical trials - the EORTC model. The EORTC Quality of Life Study Group", *Eur J Cancer*, vol. 36, no. 7, pp. 821-825.

Deleyiannis, F. W., Weymuller, E. A., Jr., & Coltrera, M. D. 1997, "Quality of life of disease-free survivors of advanced (stage III or IV) oropharyngeal cancer", *Head Neck*, vol. 19, no. 6, pp. 466-473.

Derks, W., de Leeuw, J. R., Hordijk, G. J., & Winnubst, J. A. 2003, "Elderly patients with head and neck cancer: short-term effects of surgical treatment on quality of life", *Clin.Otolaryngol*, vol. 28, pp. 399-405.

Diefenbach, G. J., Hopko, D. R., Feigon, S., Stanley, M. A., Novy, D. M., Beck, J. G., & Averill, P. M. 2003, ""minor GAD": Characteristics of sunsyndromal GAD in older adults", *Behav.Res.Ther.*, vol. 41, pp. 481-487.

Docherty, A. Experience, function and benefits of a cancer support group. Patient Education and Counseling 55[1], 87-93. 2004.
Ref Type: Journal (Full)

Doering, S., Katzlberger, F., Rumpold, G., Roessler, S., Hofstoetter, B., Schatz, D. S., Behensky, H., Krismer, M., Luz, G., Innerhofer, P., Benzer, H., Saria, A., & Schuessler, G. 2000, "Videotape preparation of patients before hip replacement surgery reduce stress", *Psychomatic Medicine*, vol. 62, pp. 365-373.

Dolbeault, S., Szporn, A., & Holland, J. C. 1999, "Psycho-oncology: where have we been? Where are we going?", *Eur J Cancer*, vol. 35, no. 11, pp. 1554-1558.

Drewett, R. F., Minns, R. J., & Sibly, T. F. 1992, "Measuring outcome of total knee replacement using quality of life indices.", *Ann R Coll Surg Engl*, vol. 74, pp. 286-289.

Dropkin, M. J. 1999, "Body image and quality of life after head and neck cancer surgery", *Cancer Pract.*, vol. 7, no. 6, pp. 309-313.

Dropkin, M. J. Anxiety, coping strategies, and coping behaviors in patients undergoing head and neck cancer surgery. Cancer Nurse 24[2], 143-148. 2001.

Ref Type: Journal (Full)

Duke, R., Campbell, B. H., Indresano, A. T., Eaton, D., Marbella, A., Myers, K. B., & Layde, P. M. Dental status and quality of life in long term head and neck cancer survivors. Laryngoscope 115, 678-683. 2005.
Ref Type: Journal (Full)

Duman, M. & Farrel, C. 2000, "The right to information," in *The POPPI Guide*, King's Fund, pp. 3-5.

Dunn, J., Steginga, S. K., Rose, P., Scott, J., & Allison, R. 2004, "Evaluating patient education materials about radiation therapy", *Patient Education and Counseling*, vol. 25, no. 3, pp. 325-332.

Eakin, E. & Strycker, L. Awareness and barriers to use of cancer support and information resources by HMO patients with breast, prostate, or colon cancer: patient and provider perspectives. Psycho-oncology 10, 103-113. 2001.
Ref Type: Journal (Full)

Edwards, D. 1998, "Head and neck cancer services: views of patients, their families and professionals", *Br.J Oral Maxillofac.Surg.*, vol. 36, pp. 99-102.

Elderkin-Thompson, V. & Waitzkin, H. 1999, "Differences in clinical communication by gender", *J Gen Intern Med* no. 14, pp. 112-121.

Endler, N. S. & Kocovski, N. L. 2001, "State and trait anxiety revisited", *Anxiety Disorders*, vol. 15, pp. 231-245.

Entwistle, V. & Watt, I. 1998, "Disseminating information about healthcare effectiveness: a survey of consumer health information services", *Quality in Health Care*, vol. 7, pp. 124-129.

Evans, S., Tritter, J., Barley, V., Daykin, N., McNeill, J., Palmer, N., Rimmer, J., Sanidas, M., & Turton, P. User involvement in UK cancer services: bridging the policy gap. European Journal of Cancer Care 12, 331-338. 2003.
Ref Type: Journal (Full)

Fallowfield, L., Ford, S., & Lewis, S. 1995, "No news is not good news: information preferences of patients with cancer", *Psychooncology.*, vol. 4, no. 3, pp. 197-202.

Fallowfield, L. & Jenkins, V. 1999, "Effective communication skills are the key to good cancer care", *Eur J Cancer*, vol. 35, no. 11, pp. 1592-1597.

Fallowfield, L. J., Hall, A., Maguire, P., Baum, M., & A'Hern, R. P. 1994, "Psychological effects of being offered choice of surgery for breast cancer", *BMJ*, vol. 309, no. 6952, p. 448.

Fawzy, F. I. 1999, "Psychosocial interventions for patients with cancer: what works and what doesn't", *Eur J Cancer*, vol. 35, no. 11, pp. 1559-1564.

Fincham, L., Copp, G., Caldwell, K., Jones, L., & Tookman, A. Supportive care: experiences of cancer patients. European Journal of Oncology Nursing 9[258], 268. 2005.
Ref Type: Journal (Full)

Finizia, C., Hammerlid, E., Westin, T., & Lindstrom, J. 1998, "Quality of life and voice in patients with laryngeal carcinoma: a posttreatment comparison of laryngectomy (salvage surgery) versus radiotherapy", *Laryngoscope*, vol. 108, no. 10, pp. 1566-1573.

Foltz, A. & Sullivan, J. 1999, "Limited Literacy revisited, implication for patient education", *Cancer Practice*, vol. 7, no. 3, pp. 145-150.

Ford, S., Schofield, T., & Hope, T. 2003, "What are the ingredients for a successful evidence-based patient choice consultation?: A qualitative study", *Social Science & Medicine*, vol. 56, pp. 589-602.

Fossa, S. D. & Dahl, A. A. 2002, "Short Form 36 and Hospital Anxiety and Depression Scale, A comparison based on patients with testicular cancer", *Journal of Psychosomatic Research*, vol. 52, pp. 79-87.

Frazer, L. & Lawley, M. 2000, *Questionnaire design and administration: A practical guide* John Wiley & Sons Australia, Ltd.

Funk, G. F., Karnell, L. H., Dawson, C. J., Means, M. E., Colwill, M. R., Gliklich, R. E., Alford, E. L., & Stewart, M. 1997, "Baseline and post treatment assessment of the general health status of head and neck cancer patients compared with united states population norms", *Head & Neck*, vol. December, pp. 675-683.

Gallant, M. & Coutts, L. Evaluation of an oncology outpatient orientation program: patient satisfaction and outcomes. Support Care Cancer 11[12], 800-805. 2003.
Ref Type: Journal (Full)

Gatherer, L. 2000, "Patient information on cancer. Newspaper read is good predictor of information needs", *BMJ*, vol. 321, no. 7252, p. 48.

Gattellari, M., Butow, P., & Tattersall, M. 2001, "Sharing decision in cancer care", *Social Science & Medicine*, vol. 52, pp. 1865-1878.

Gellrich, N., Schimming, R., Bremerich, A., & Kugler, J. Pain, function, and psychologic outcome before, during, and after intraoral tumor resection. J Oral Maxillofac.Surg. 60, 772-777. 2002.
Ref Type: Journal (Full)

Genden, E., Rinaldo, A., Shaha, A., Clayman, G., Werner, J., Suarez, C., & Ferlito, A. Treatment consideration for head and neck cancer in the elderly. The Journal of Laryngology and Otology 119, 169-174. 2005.
Ref Type: Journal (Full)

Gesell, S. & Gregory, N. Identifying priority actions for improving patient satisfaction with outpatient cancer care. Journal of nursing care quality 19[3], 226-233. 2004.
Ref Type: Journal (Full)

Gleich, L. L., Collins, C. M., Gartside, P. S., Gluckman, J. L., Barrett, W. L., Wilson, K. M., Biddinger, P. W., & Redmond, K. P. 2003, "Therapeutic decision making in stage III and IV head and neck squamous cell carcinoma", *Arch.Otolaryngol.Head Neck Surg.*, vol. 129, pp. 26-35.

Gliklich, R. E., Goldsmith, T. A., & Funk, G. F. 1997, "Are head and neck specific quality of life measures necessary?", *Head Neck*, vol. 19, no. 6, pp. 474-480.

Goldman, H. H. 2000, *Review of general psychiatry*, fifth edition edn, Lang Medical Book/McGraw-Hill.

Gourdji, I., McVey, L., & Loiselle, C. Patients' satisfaction and importance ratings of quality in outpatient oncology center. Journal of nursing care quality 18[1], 43-55. 2003.
Ref Type: Journal (Full)

Greer, S. 2002, "Psychosocial intervention. The gap between research and practice", *Acta Oncol.*, vol. 41, no. 3, pp. 238-243.

Grobbelaar, E. J., Owen, S., Torrance, A. D., & Wilson, J. A. Nutritional challenges in head and neck cancer. Ciln Otolaryngol 29, 307-313. 2004.
Ref Type: Journal (Full)

Grunfeld, E., Fitzpatrick, R., & Mant, D. 1999, "Comparison of breast cancer patients satisfaction with follow-up in primary care versus specialist care: results from a randomized controlled trial.", *British Journal of General Practice*, vol. 49, no. 446, pp. 705-710.

Hagerty, R., Butow, P., Ellis, P., Lobb, E., Pendlebury, S., Leighl, N., MacLeod, C., & Tattersall, M. Communicating with realism and hope: incurable cancer patients' views on disclosure of prognosis. Journal of Clinical Oncology 23[6], 1278-1288. 2005.
Ref Type: Journal (Full)

Haggmark, C., Bohman, L., Ilmoni-Brandt, K., Naslund, I., Sjoden, P. O., & Nilsson, B. Effects of information supply on satisfaction with information and quality of life in cancer patients receiving curative radiation therapy. Patient Education and Counseling 45[3], 173-179. 2001.
Ref Type: Journal (Full)

Hagopian, G. A. 1996, "The effects of informational audiotapes on knowledge and self-care behaviors of patients undergoing radiation therapy", *Oncol Nurs Forum*, vol. 23, no. 4, pp. 697-700.

Hammerlid, E., Ahlner-Elmqvist, M., Bjordal, K., Biorklund, A., Evensen, J., Boysen, M., Jannert, M., Kaasa, S., Sullivan, M., & Westin, T. 1999a, "A prospective multicentre study in Sweden and Norway of mental distress and psychiatric morbidity in head and neck cancer patients", *Br.J Cancer*, vol. 80, no. 5-6, pp. 766-774.

Hammerlid, E., Mercke, C., Sullivan, M., & Westin, T. 1997, "A prospective quality of life study of patients with oral or pharyngeal carcinoma treated with external beam irradiation with or without brachytherapy", *Oral Oncol.*, vol. 33, no. 3, pp. 189-196.

Hammerlid, E., Mercke, C., Sullivan, M., & Westin, T. 1998, "A prospective quality of life study of patients with laryngeal carcinoma by tumor stage and different radiation therapy schedules", *Laryngoscope*, vol. 108, no. 5, pp. 747-759.

Hammerlid, E., Persson, L., Sullivan, M., & Westin, T. Quality of life effects of psychosocial intervention in patients with head and neck cancer. Otolaryngol.Head Neck Surg. 120, 507-516. 1999b.
Ref Type: Journal (Full)

Hammerlid, E., Silander, E., Hornestam, L., & Sullivan, M. 2001a, "Health related quality of life three years after diagnosis of head and neck cancer-a longitudinal study", *Head & Neck*, vol. 23, pp. 113-125.

Hammerlid, E. & Taft, C. 2001b, "Health related quality of life in long term head and neck cancer survivors: a comparison with general population norms", *Br.J Cancer*, vol. 84, no. 2, pp. 149-156.

Han, W. T., Koopman, C. K., Classen, A. J., Michel, M., Brennan-O'Neill, E., & Spiegel, D. Breast cancer and problems with medical interactions: relationships with traumatic stress, emotional self-efficacy, and social support. Psycho-oncology 14[4], 318-330. 2005.
Ref Type: Journal (Full)

Harding, R., Higginson, I., & Donaldson, N. The relationship between patient characteristics and carer psychological status in home palliative cancer care. Support Care Cancer 11, 638-643. 2003.
Ref Type: Journal (Full)

Harris, K. A. 1998, "The informational needs of patients with cancer and their families", *Cancer Pract.*, vol. 6, no. 1, pp. 39-46.

Hassan, S. J. & Weymuller, E. A., Jr. 1993, "Assessment of quality of life in head and neck cancer patients", *Head Neck*, vol. 15, no. 6, pp. 485-496.

Hassanein, K. A., Musgrove, B. T., & Bradbury, E. 2001, "Functional status of patients with oral cancer and its relation to style of coping, social support and psychological status", *Br.J Oral Maxillofac.Surg.*, vol. 39, pp. 340-345.

Hay, J. L., Ostroff, J. S., Cruz, G. D., LeGeros, R. Z., Kenigsberg, H., & Franklin, D. M. 2002, "Oral cancer risk perception among participants in an oral cancer screening program", *Cancer Epidemioogy, Biomarkers & Prevention*, vol. 11, pp. 155-158.

He, G. & Liu, S. Quality of life and coping styles in Chinese nasopharyngeal cancer patients after hospitalization. Cancer Nurse 28[3], 179-186. 2005.
Ref Type: Journal (Full)

Heaney, D., Wyke, S., Wilson, P., Elton, R., & Rutledge, P. 2001, "Assessment of impact of information booklet on the use of healthcare services: randomised controlled trial", *BMJ*, vol. 322, pp. 1-5.

Herrmann, C. 1997, "International experience with the Hospital Anxiety and Depression scale-A review of validation data and clinical results", *Journal of Psychosomatic Reasearch*, vol. 42, no. 1, pp. 17-41.

Hindle, I., Downer, M. C., & Speight, P. M. 1996, "The epidemiology of oral cancer", *Br.J Oral Maxillofac.Surg.*, vol. 34, no. 5, pp. 471-476.

Holland, J. C. 1999, "Update: NCCN practice guidelines for the management of psychosocial distress", *Oncologica*, vol. 13, pp. 459-507.

Holloway, R., Hellewell, J., Marbella, A. M., Layde, P. M., Myers, K. B., & Campbell, B. H. Psychosocial effects in long-term head and neck cancer survivors. Head & Neck [April], 281-288. 2005.
Ref Type: Journal (Full)

Hope, S., Williams, A. S., & Lunn, D. 2000, "Information provision to cancer patients: a practical example of identifying the need for changes in practice from the Dorset Cancer Centre", *European Journal of Cancer Care* no. 9, pp. 238-242.

Horowitz, A. M., Goodman, H. S., Yellowitz, J. A., & Nourjah, P. A. 1996, "The need for health promotion in oral cancer prevention and early detection", *J Public Health Dent.*, vol. 56, no. 6, pp. 319-330.

Horowitz, M. J. 1997, in *Stress response syndrome*, 3rd edition edn, J. Aronson, ed..

Humphris, G. M., Duncalf, M., Holt, D., & Field, E. A. 1999, "The experimental evaluation of an oral cancer information leaflet", *Oral Oncol.*, vol. 35, no. 6, pp. 575-582.

Humphris, G. M., Ireland, R. S., & Field, E. A. 2001, "Randomised trial of the psychological effect of information about oral cancer in primary care settings", *Oral Oncol.*, vol. 37, no. 7, pp. 548-552.

Jefferson, J. W. 1996, "Social phobia: everyone's disorder?", *J Clin Psychiatry*, vol. 57, no. 6s, pp. 28-32.

Jenkinson, C., Layte, R., Wright, L., & Coulter, A. 1996, *The U.K. SF-36: An analysis and interpretation manual.*

Johnston, M., Pollard, B., & Hennessey, P. 2000, "Construct validation of the hospital anxiety and depression scale with clinical population", *Journal of Psychosomatic Reasearch*, vol. 48, pp. 579-584.

Jones, R., Hampshire, A., Tweddle, S., Moult, B., & Hill, A. 2001, "The clinician's role in meeting patients information needs: suggested learning outcomes", *Medical Education*, vol. 35, no. 565, p. 571.

Jones, R., Pearson, J., McGregor, S., Gilmour, W. H., Atkinson, J. M., Barrett, A., Cawsey, A. J., & McEwen, J. 1999, "Cross sectional survey of patients' satisfaction with information about cancer", *BMJ*, vol. 319, no. 7219, pp. 1247-1248.

Kaplan, H. I. & Sadock, B. J. 1995, *Comprehensive textbook of psychiatry*, 6th edition edn, Williams & Wilkins.

Katz, M. R., Irish, J. C., Devins, G. M., Rodin, G. M., & Gullane, P. J. 2003, "Psychosocial adjustment in head and neck cancer: the impact for disfigurement, gender and social support", *Head & Neck*, vol. February, pp. 103-112.

Kerrigan, D. D., Thevasagayam, R. S., Woods, T. O., Mc, W., I, Thomas, W. E., Shorthouse, A. J., & Dennison, A. R. 1993, "Who's afraid of informed consent?", *BMJ*, vol. 306, no. 6873, pp. 298-300.

Kessler, R. C., DuPont, R. L., Berglund, P., & Wittchen, H. U. 1999, "Impairment in pure and comorbid generalized anxiety disorder and major depression at 12 months in two national surveys", *Am J Psychiatry*, vol. 156, no. 12, pp. 1915-23.

Kiebert, G. M. 1997, "Quality of life as an outcome measure in cancer clinical trials", *Eur Urol.*, vol. 31 Suppl 1, pp. 56-64.

Kindler, C. H., Harms, C., Amsler, F., Ihde-Scholl, T., & Scheidegger, D. 2000, "The visual analog scale allows effective measurement of preoperative anxiety and detection of patients' anesthetic concerns", *Anesth.Analg.*, vol. 90, no. 3, pp. 706-712.

Kirk, P., Kirk, I., & Kristjanson, L. What do patients receiving palliative care for cancer and their families want to be told? A Canadian and Australian qualitative study. BMJ 328, 1343. 2004.
Ref Type: Journal (Full)

Klug, C. & Neuburg, C. 2002, "Quality of life 2-10 years after combined treatment for advanced oral and oro-pharyngeal cancer", *Int.J.Oral Maxillofac.Surg*, vol. 30, pp. 664-669.

Kogan, J. N., Edelstein, B. A., & McKee, D. R. 2000, "Assessment of anxiety in older adults: current status", *Journal of Anxiety Disorders*, vol. 14, no. 2, pp. 109-132.

Konski, A., Brekey, B. A., Ang, K. K., & Fu, K. K. Effect of education level on outcome of patients treated on Radiation Therapy Oncology Group protocol 90-03. Cancer 98, 1497-1503. 2003.
Ref Type: Journal (Full)

Krouse, H. J. 2001, "Video modelling to educate patients", *Journal of Advanced Nursing*, vol. 33, no. 6, pp. 748-757.

Kugaya, A., Akechi, T., Okamura, H., Mikami, I., & Uchitomi, Y. 1999, "Correlates of depressed mood in ambulatory head and neck cancer patients", *Psychooncology.*, vol. 8, no. 6, pp. 494-499.

Kumar, P. & Clark, M. 2002, "Psychological medicine," in *Clinical medicine*, Fifth Edition edn, W. B. Saunders.

Kuntz, A. L. & Weymuller, E. A., Jr. 1999, "Impact of neck dissection on quality of life", *Laryngoscope*, vol. 109, no. 8, pp. 1334-1338.

La Vecchia, C., Tavani, A., Franceschi, S., Levi, F., Corrao, G., & Negri, E. 1997, "Epidemiology and prevention of oral cancer", *Oral Oncol.*, vol. 33, no. 5, pp. 302-312.

Lampic, C., Thurfjell, E., Bergh, J., & Sjoden, P. O. 2001, "Short- and long-term anxiety and depression in women recalled after breast cancer screening.", *Eur J Cancer*, vol. 37, no. 4, pp. 463-469.

Langdon, J. D. 1995, "Oral cancer: raising the level of awareness", *Dent.Update.*, vol. 22, no. 7, pp. 269-270.

Larsson, M., Henelin, B., & Athlin, E. Live experience of eating problems for patients with head and neck cancer during radiotherapy. J Clin Nurs 12, 562-570. 2003.
Ref Type: Journal (Full)

Lauver, D. R., Ward, S. E., Heidrich, S. M., Keller, M. L., Bowers, B. J., Brennan, P. F., Kirchhoff, K. T., & Wells, T. J. 2002, "Patient-centered interventions", *Reaserch in Nursing & Health*, vol. 25, pp. 246-255.

Laverick, S., Brown, J. S., Vaughan, E. D., & Rogers, S. N. The impact of neck dissection on health related quality of life. Arch.Otolaryngol.Head Neck Surg. 130, 149-154. 2004.
Ref Type: Journal (Full)

Lazarus, R. S. 1991, *Emotion and adaptation* Oxford University Press, London.

Lennox, A. S., Osman, L. M., Reiter, E., Robertson, R., Friend, J., McCann, I., Skatun, D., & Donnan, P. T. 2001, "Cost effectiveness of computer tailored and non-tailored smoking cessation letters in general practice: randomized controlled trial", *BMJ*, vol. 322, pp. 1-7.

Lewis, D. 1999, "Computer-based approaches to patient education: a review of the literature", *J Am.Med.Inform.Assoc.*, vol. 6, no. 4, pp. 272-282.

Leydon, G. M., Boulton, M., Moynihan, C., Jones, A., Mossman, J., Boudioni, M., & McPherson, K. 2000, "Cancer patients' information needs and information seeking behaviour: in depth interview study", *BMJ*, vol. 320, no. 7239, pp. 909-913.

Liedholm, H., Linne, A. B., & Agelii, L. 1996, "The development of an interactive education program for heart failure patients: the Kodak Photo CD Portfolio concept", *Patient Education and Counseling*, vol. 29, pp. 199-206.

Lindqvist, O., Widmark, A., & Rasmussen, B. Meaning of the phenomenon of fatigue as narrated by 4 patients with cancer in palliative care. Cancer Nurse 27[3], 237-243. 2004.
Ref Type: Journal (Full)

Little, P., Dorward, M., Warner, G., Moore, M., Stephens, K., Senior, J., & Kendrick, T. 2004, "Randomised controlled trial of effect of leaflets to empower patients is consultation in primary care", *BMJ*, vol. 328, no. 441-.

Llewellyn, C. D., McGurk, M., & Weinman, J. Are psychosocial and behavioural factors related to health related quality of life in patients with head and neck cancer? A systematic review. Oral Oncology 41, 440-454. 2005.
Ref Type: Journal (Full)

Lloyd, S., Devesa-Martinez, P., Howard, D. J., & Lund, V. J. 2003, "Quality of life of patients undergoing surgical treatment of head and neck malignancy", *Clin.Otolaryngol*, vol. 28, pp. 524-532.

Mackenzie, J., Ah-See, K., Thakker, N., Sloan, P., Maran, A. G., Birch, J., & Macfarlane, G. J. 2000, "Increasing incidence of oral cancer amongst young persons: what is the aetiology?", *Oral Oncol.*, vol. 36, no. 4, pp. 387-389.

Maguire, P. 1995, "Psychosocial intervention to reduce affective disorders in cancer patients: research priorities", *Psycho-oncology*, vol. 4, pp. 113-119.

Maldonato, A., Segal, P., & Golay, A. 2001, "The diabetes education study group and its activities to improve the education of people with diabetes in Europe", *Patient Education and Counseling*, vol. 44, pp. 87-94.

Mallinger, J. B., Griggs, J. J., & Shields, C. G. Patient-centered care and breast cancer survivors satisfaction with information. Patient Education and Counseling 57, 342-349. 2005.
Ref Type: Journal (Full)

Mays, N. & Pope, C. Qualitative research in health care: Assessing quality in qualitative research. BMJ 320, 50-52. 2000.
Ref Type: Journal (Full)

Mazor, K. & Billings-Gagliardi, S. 2003, "Does reading about stroke increase stroke knowledge? The impact of different print materials", *Patient Education and Counseling*, vol. 51, pp. 207-215.

McHugh, P., Lewis, S., Ford, S., Newlands, E., Rustin, G., Coombes, C., Smith, D., O'Reilly, S., & Fallowfield, L. 1995, "The efficacy of audiotapes in promoting psychological well-being in cancer patients: a randomised, controlled trial", *Br.J Cancer*, vol. 71, no. 2, pp. 388-392.

McLane, L., Jones, C., Lydiatt, W., Laydiatt, D., & Richards, A. Taking away the fear: A grounded theory study of cooperative care in the treatment of head and neck cancer. Psycho-oncology 12, 474-490. 2003.
Ref Type: Journal (Full)

McPherson, C., Higginson, I., & Hearn, J. 2001, "Effective methods of giving information in cancer: a systematic review of randomized controlled trials", *Journal of Public Health Medicine*, vol. 23, no. 3, pp. 227-234.

Mennin, D. S., Heimberg, R. G., & Jack, M. S. 2000, "Comorbid generalized anxiety disorder in primary phobia: symptoms severity, functional impairment, and treatment response", *Journal of Anxiety Disorders*, vol. 14, no. 4, pp. 325-343.

Meredith, C., Symonds, P., Webster, L., Lamont, D., Pyper, E., Gillis, C. R., & Fallowfield, L. 1996, "Information needs of cancer patients in west Scotland: cross sectional survey of patients' views", *BMJ*, vol. 313, no. 7059, pp. 724-726.

Mesters, I., Van Den Borne, B., De Boer, M. F., & Pruyn, J. F. 2001, "Measuring information needs among cancer patients", *Patient Education and Counseling*, vol. 43, pp. 253-262.

Meunier, F. 1997, "the challenges and opportunities of cancer clinical research: EORTC Perspectives", *Eur J Cancer*, vol. 33, suppl. 4, pp. 23-30.

Meyer, T. J. & Mark, M. M. 1995, "Effect of psychosocial intervention with adult cancer patients: a meta-analysis of randomized experiment", *Health Psychol.*, vol. 14, pp. 101-108.

Mills, M. E. & Davidson, R. 2002, "Cancer patients' sources of information: use and quality issues", *Psycho-oncology* no. 11, pp. 371-378.

Mills, M. E. & Sullivan, K. 2000, "Patients with operable oesophageal cancer: their experiance of information-giving in a regional thoracic unit", *J Clin Nurs* no. 9, pp. 236-246.

Miyata, H., Tachimori, H., Takahashi, M., Saito, T., & Kai, I. Disclosure of cancer diagnosis and prognosis: a survey of the general public's attitude toward doctors and family holding discretionary power. BMC Medical Ethics 5[7]. 2004.
Ref Type: Journal (Full)

Mok, E., Chan, F., Chan, V., & Yeung, E. Family experience caring for terminally ill patients. Cancer Nurse 26[4], 267-275. 2003.
Ref Type: Journal (Full)

Molassiotis, A. & Chan, C. W. H. Fatigue pattern in Chinese patients receiving radiotherapy. European Journal of Oncology Nursing 8[334], 340. 2004.
Ref Type: Journal (Full)

Moore, R. J., Chamberlain, R. M., & Khuri, F. R. A qualitative study of head and neck cancer. Support Care Cancer 12[5], 338-346. 2004a.
Ref Type: Journal (Full)

Moore, R. J., Chamberlain, R. M., & Khuri, F. R. Communicating suffering in primary stage head and neck cancer. Eur J Cancer Care 13, 53-64. 2004b.
Ref Type: Journal (Full)

Morgan III, C. A., Wnag, S., Ramusson, A., Hazlett, G., Anderson, G., & Charney, D. S. 2001, "Relationship among plasma cortisol, catecholamines, neuropeptide Y, and human performance during exposure to uncontrollable stress", *Psychosomatich Medicine*, vol. 63, pp. 412-422.

Morgan, R., Tsang, J., Harrington, N., & Fook, L. 2001, "Survey of hospital doctors' attitude and knowledge of oral conditions in older patients", *Postgraduate Medical Journal*, vol. 77, pp. 392-394.

Morris, J. 1993, *the quality of life of head and neck cancer patients: A review of the literature*, university of york, center for health economics, 72.

Mossman, J., Boudioni, M., & Slevin, M. L. 1999a, "Cancer information: a cost-effective intervention", *Eur J Cancer*, vol. 35, no. 11, pp. 1587-1591.

Mossman, J. & Slevin, M. 1999b, "Psychosocial oncology: the state of the art at the end of the millennium", *Eur J Cancer*, vol. 35, no. 11, p. 1553.

Mykletun, A., Stordal, E., & Dahl, A. A. 2001, "Hospital Anxiety and Depression (HAD) scale: factor structure, item analysis and internal consistency in a large population", *Br J Psychiatry*, vol. 179, pp. 540-544.

Naila, S., Bhatti, N. S., & Downer, M. C. 1995, "public knowledge and attitudes of oral cancer: a pilot investigation.", *Journal of Institute of Health Education*, vol. 31, pp. 112-117.

Nair, M. G., Hickok, J. T., Rosco, J. A., & Morrow, G. R. 2000, "Sources of information used by patients to learn about chemotherapy side effects", *J Cancer Educ* no. 15, pp. 19-22.

Newell, R. 2000, "Psychological difficulties amongst plastic surgery ex-patients following surgery to the face: a survey", *Br J Plast Surg*, vol. 53, no. 5, pp. 386-392.

Newell, R. & Marks, I. 2000, "Phobic nature of social difficulty in facially disfigured people", *Br J Psychiatry*, vol. 176, pp. 177-181.

Newell, R., Ziegler, L., Stafford, N., & Lewin, R. 2004, "The information needs of head and neck cancer patients", *Ann R Coll Surg Engl*, vol. 86, pp. 407-410.

Nguyen, N., Frank, C., Moltz, C., Vos, P., Smith, H., Karlsson, U., Dutta, S., Midyett, A., barloon, J., & Sallah, S. Impact of dysphagia on quality of life after treatment of head and neck cancer. Int.J.Radiation Oncology Biol.Phys. 61[3], 772-778. 2005.
Ref Type: Journal (Full)

NHS, E. 2004, *Improving Outcome in Head and Neck Cancer.*

Nordgren, M., Abendstein, H., Jannert, M., Boysen, M., Ahlner-Elmqvist, M., Silander, E., Bjordal, K., & Hammerlid, E. 2003, "Health-Related quality of life five years after diagnosis of laryngeal carcinoma", *Int.J.Radiation Oncology Biol.Phys.*, vol. 56, no. 5, pp. 1333-1343.

Northouse, L., Kershaw, T., Mood, D., & Schafenacker, A. Effect of a family intervention on the quality of life of women with recurrent breast cancer and their family caregivers. Psycho-oncology 14[6], 478-491. 2005.
Ref Type: Journal (Full)

Northouse, L., Schafenacker, A., Walker, J., Mood, D., Mellon, S., Galvin, E., Harden, J., & Freeman-Gibb, L. A family-based program of care for women with recurrent breast cancer and their family members. Oncol Nurs Forum 29[10], 1411-1419. 2002.

Ref Type: Journal (Full)

Oermann, M. H. 2003, "Using health web sites for patient education", *Wound Care*, vol. 30, no. 217, p. 223.

Ohayon, M. M. & Lader, M. H. 2002, "Use of psychotropic medication in the general population of France, Germany, Italy, and the United Kingdom", *J Clin Psychiatry*, vol. 63, no. 9, pp. 817-825.

Ong, L. M. L., Visser, M. R. M., Lammes, F. B., & de Haes, J. C. J. M. 2000, "Doctor-patient communication and cancer patient's quality of life and satisfaction", *Patient Education and Counseling*, vol. 41, no. 2, pp. 145-156.

Ong, L. M. L., Visser, M. R. M., van Zuuren, F. J., Rietbroek, R. C., Lammes, F. B., & de Haes, J. C. J. M. 1999, "Cancer patients' coping styles and doctor-patients communication", *Psycho-oncology* no. 8, pp. 155-166.

Osoba, D. 1999, "What has been learned from measuring health-related quality of life in clinical oncology", *Eur J Cancer*, vol. 35, no. 11, pp. 1565-1570.

Owen, J. E., Klapow, J. C., Hicken, B., & Tucker, D. C. 2001a, "Psychosocial interventions for cancer: review and analysis using a three-tiered outcomes model", *Psycho-oncology*, vol. 10, pp. 218-230.

Owen, J. E., Klapow, J. C., Hicken, B., & Tucker, D. C. 2001b, "Psychosocial interventions for cancer: review and analysis using a three-tired outcomes model", *Psycho-oncology*, vol. 10, pp. 218-230.

Parker, P., Baile, W., De Moor, C., & Cohen, L. Psychosocial and demographic predictors of quality of life in a large sample of cancer patients. Psychooncology. 12, 183-193. 2003.
Ref Type: Journal (Full)

Patient liaison Group, R. E. 2003, *Patients rights and responsibilities*, Patient liaison Group-Royal College of Surgeons (England), http://www.rcs.

Penson, R., Talsania, S., Chabner, B. A., & Lynch, T. Help me Help you: support groups in cancer therapy. The Oncologist 9, 217-225. 2004.
Ref Type: Journal (Full)

Petruson, K. M., Silander, E., & Hammerlid, E. 2003, "Effect of psychosocial intervention on quality of life in patients with head and neck cancer", *Head & Neck*, vol. 25, pp. 576-584.

Pileggi, C., Carbone, V., Pavia, M., & Angelillo, I. F. Patients' perception and related behaviours on role of primary care physician in Italy. The European Journal of Public Health 14[3], 258-260. 2004.
Ref Type: Journal (Full)

Pourel, N., Peiffert, D., Lartigau, E., Desandes, E., Luporsi, E., & Conroy, T. 2002, "Quality of life in long-term survivors of oropharynx carcinoma", *Int.J.Radiation Oncology Biol.Phys.*, vol. 54, no. 3, pp. 742-751.

Pruitt, B. T., Waligora-Serafin, B., McMahon, T., Byrd, G., Besselman, L., Kelly, G. M., Drake, D. A., & Cuellar, D. 1993, "An educational intervention for newly diagnosed cancer patients undergoing radiotherapy", *Psycho-oncology*, vol. 2, pp. 55-62.

Quality of life unit, E. d. C. The EORTC Quality of Life Study Group manual: Scoring procedure. http://www.eortc.be/home/qol . 2001.
Ref Type: Electronic Citation

Rankin, S., Newell, R., Sanson-Fisher, R. W., & Girgis, A. Consumer participation in the development of psychosocial clinical practice guidelines: opinions of women with breast cancer. Eur J Cancer Care 9[2], 97-104. 2000.
Ref Type: Journal (Full)

Rapoport, Y., Kreitler, S., Chaitchik, S., Algor, R., & Weissler, K. 1993, "Psychosocial problems in head-and-neck cancer patients and their change with time since diagnosis", *Ann.Oncol.*, vol. 4, no. 1, pp. 69-73.

Razavi, D. & Delvaux, N. 1997, "Communication skills and psychological training in oncology", *Eur J Cancer*, vol. 33 Suppl 6, p. S15-S21.

Razavi, D. & Stiefel, F. 1994a, "Common psychiatric disorders in cancer patients. I: Adjustment disorders in cancer patients", *Support Care Cancer*, vol. 2, no. 4, pp. 223-232.

Razavi, D. & Stiefel, F. 1994b, "Common psychiatric disorders in caner patients. I: Adjustment disorders and depressive disorders", *Support Care Cancer*, vol. 2, no. 4, pp. 223-232.

Ream, E., Browne, N., Glaus, A., Knipping, C., & Frei, I. 2003, "Quality and efficacy of educational materials on cancer-related fatigue: view of patients from two European countries", *European Journal of Oncology Nursing*, vol. 7, no. 2, pp. 99-109.

Rehse, B. & Pukrop, R. 2003, "Effects in psychosocial intervention on quality of life in adult cancer patients: meta-anlaysis of 37 published controlled outcome studies", *Patient Education and Counseling*, vol. 50, no. 2, pp. 179-186.

Richards, M. A., Ramirez, A. J., Degner, L. F., Fallowfield, L. J., Maher, E. J., & Neuberger, J. 1995, "Offering choice of treatment to patients with cancers. A review based on a symposium held at the 10th annual conference of The British Psychosocial Oncology Group, December 1993", *Eur J Cancer*, vol. 31A, no. 1, pp. 112-116.

Robinson, E., Rumsey, N., & Partridge, J. 1996, "An evaluation of the impact of social interaction skills training for facially disfigured people", *Br J Plast Surg*, vol. 49, no. 5, pp. 281-289.

Rogers, M., warshaw, M. G., Goisman, R. M., Goldenberg, I., Rodriguez-villa, F., Mallya, G., Freeman, S. A., & Keller, M. B. 1999a, "Comparing primary and secondary generalized

anxiety disorder in a long-term naturalistic study of anxiety disorders", *Depression and Anxiety*, vol. 10, pp. 1-7.

Rogers, S. N., Fisher, S. E., & Woolgar, J. A. 1999b, "A review of quality of life assessment in oral cancer", *Int.J.Oral Maxillofac.Surg*, vol. 28, pp. 99-117.

Rogers, S. N., Hannah, L., Lowe, D., & Magennis, P. 1999c, "Quality of life 5-10 years after primary surgery for oral and oro-pharyngeal cancer", *J Craniomaxillofac.Surg.*, vol. 27, no. 3, pp. 187-191.

Rogers, S. N., Humphris, G., Lowe, D., Brown, J. S., & Vaughan, E. D. 1998a, "The impact of surgery for oral cancer on quality of life as measured by the Medical Outcomes Short Form 36", *Oral Oncol.*, vol. 34, no. 3, pp. 171-179.

Rogers, S. N., Lowe, D., Brown, J. S., & Vaughan, E. D. 1998b, "A comparison between the University of Washington head and neck disease-specific measure and the Medical Short Form 36, EORTC QOQ-C33 and EORTC Head and Neck 35", *Oral Oncol.*, vol. 34, pp. 361-372.

Rogers, S. N., Lowe, D., Brown, J. S., & Vaughan, E. D. 1999d, "The University of Washington head and neck cancer measure as a predictor of outcome following primary surgery for oral cancer", *Head Neck*, vol. 21, no. 5, pp. 394-401.

Rogers, S. N., Lowe, D., Fisher, S. E., Brown, J. S., & Vaughan, E. D. 2002, "Health-Related Quality of Life and clinical function after primary surgery for oral cancer", *Br.J Oral Maxillofac.Surg.*, vol. 40, no. 1, pp. 11-18.

Rogers, S. N., Lowe, D., & Humphris, G. 2000, "Distinct patient groups in oral cancer: a prospective study of perceived health status following primary surgery", *Oral Oncol.*, vol. 36, no. 6, pp. 529-538.

Rondeau, K. V. Managing the clinical wait: an important quality of care challenge. Journal of nursing care quality 13[2], 11-20. 1998.
Ref Type: Journal (Full)

Ross, L., Boesen, E. H., Dalton, S. O., & Johansen, C. 2002, "Mind and cancer: Does psychosocial intervention improve survival and psychological well-being?", *Eur J Cancer*, vol. 38, no. 11, pp. 1447-1457.

Roter, D. L. & Hall, J. A. 1998, "Why physician gender matters in shaping the physician-patient relationship", *J Women's Health* no. 7, pp. 1093-1097.

Roter, D. L., Stewart, M., Putnam, S. M., Lipkin, M., Stiles, W., & Inui, T. S. 1997, "Communication patterns of primary care physicians", *J Am Med Assoc* no. 227, pp. 350-356.

Ruhl, C. M., Gleich, L. L., & Gluckman, J. L. 1997, "Survival, function, and quality of life after total glossectomy", *Laryngoscope*, vol. 107, no. 10, pp. 1316-1321.

Rumsey, N., Clark, A., White, P., Wyn-Williams, M., & Garlick, W. Altered body image: appearance related concerns of people with visible disfigurement. J Adv Nurs 48[5], 443-453. 2004.
Ref Type: Journal (Full)

Saares, P. & Suominent, T. Experiences and resources of breast cancer patients in short-stay surgery. European Journal of Cancer Care 14[1], 43-52. 2005.
Ref Type: Journal (Full)

Schliephake, H., Ruffert, K., & Schneller, T. 1996, "Prospective study of the quality of life of cancer patients after intraoral tumor surgery", *J Oral Maxillofac.Surg.*, vol. 54, no. 6, pp. 664-669.

Semple, C. & McGowan, B. 2002, "Need for appropriate written information for patients, with particular reference to head and neck cancer", *Journal of Clinical Nursing*, vol. 11, pp. 585-593.

Semple, C., Sullivan, K., Dunwoody, L., & Kernohan, W. G. Psychosocial intervention for patients with head and neck cancer: past, present, and future. Cancer Nurse 27[6], 434-441. 2004.
Ref Type: Journal (Full)

Sheard, T. & Maguire, P. 1999, "The effect of psychological interventions on anxiety and depression in cancer patients: results of two meta-analysis", *Br.J Cancer*, vol. 80, no. 11, pp. 1770-1780.

shepherd, K. L. & Fisher, S. E. 2004, "Prospective evaluation of quality of life in patients with oral and pharyngeal cancer: from diagnosis to three months post-treatment", *Oral Oncol.*, vol. 40, pp. 751-757.

Sherman, A. C., Simonton, S., Adams, D. C., Vural, E., & Hanna, E. 2000, "Coping with head and neck cancer during different phases of treatment", *Head Neck*, vol. 22, no. 8, pp. 787-793.

Shilling, V., Jenkins, V., & Fallowfield, L. 2003, "Factors affecting patient and clinician satisfaction with the clinical consultation: can communication skills training for clinicians improve satisfaction?", *Psycho-oncology*, vol. 12, pp. 599-611.

Silverstone, P. H. Poor efficacy of the Hospital and Anxiety and Depression Scale in the diagnosis of major depressive disorder in both medical and psychiatric patients. Journal of Psychosomatic Research 38[5], 441-450. 1994.
Ref Type: Journal (Full)

Sjoling, M., Nordahl, G., Olofsson, N., & Asplund, K. The impact of preoperative information on state anxiety, postoperative pain and satisfaction with pain management. Patient Education and Counseling 51, 169-176. 2003.
Ref Type: Journal (Full)

Slade, T. & Andrews, G. 2001, "DSM-IV and ICD-10 generalized anxiety disorder: discrepant diagnosis and associated disability", *Soc Psychiatry Psychiatr epidemiol*, vol. 36, pp. 45-51.

Smart, J. & Burling, D. 2001, "Radiology and the Internet: a systematic review of patient information resources", *Clinical Radiology*, vol. 56, pp. 867-870.

Snaith, R. P. The Hospital Anxiety and Depression Scale. Health and Quality of Life Outcomes 1, 29. 2003.
Ref Type: Journal (Full)

Spiegel, D. 1994, "Psychosocial Support for cancer patients with cancer", *Cancer*, vol. 74, no. S4, pp. 1453-1457.

Spitzer, R. L. & Wakefield, J. C. 1999, "DSM-IV Diagnostic criterion for clinical significance: Does it help solve the false positive problems?", *Am J Psychiatry*, vol. 156, no. 12, pp. 1856-1864.

Stafford, N., Lewin, R., Nash, P., & Hardman, G. F. 2001, "surgeon information giving practice prior to laryngectomy: a national survey", *Ann R Coll Surg Engl*, vol. 83, pp. 179-185.

Stak, D., Kiely, M., Morley, S., Selby, P., & House, A. 2004, "Reassurance and the anxious cancer patients", *Br.J Cancer*, vol. 91, no. 5, pp. 893-899.

Stewart, T. M. Light on body image treatment: acceptance through mindfulness. Behav Modif 28[6], 783-811. 2004.
Ref Type: Journal (Full)

Street Jr, R. L. 2002, "Gender differences in health care provider-patient communication: are they due to style, stereotypes, or accommodation?", *Patient Education and Counseling* no. 48, pp. 201-206.

Street, E., Drew, P. J., Carleton, P. J., Monson, J. R., Fox, J. N., Duthie, G. S., & Kerin, M. J. 1998, "Interactive multimedia information program for use by breast-care nurses--a patient acceptability study", *Eur J Surg.Oncol.*, vol. 24, no. 6, pp. 496-498.

Stromberg, A. 2002, "Educating nurses and patients to manage heart failure", *European Journal of Cardiovasculer Nursing*, vol. 1, pp. 33-40.

Taylor, E. Spiritual complimentary therapies in cancer care. Semin.Oncol.Nurs 21[3], 159-163. 2005.
Ref Type: Journal (Full)

Taylor, E., Ismail, S., Hills, H., & Ainsworth, S. Multicomponent psychosocial support for newly diagnosed cancer patients: Participants' views. Int J Palliat Nurs 10[6], 287-195. 2004a.
Ref Type: Journal (Full)

Taylor, J. C., Terrel, J. E., Ronis, D. L., Fowler, K. E., Bishop, C., Lambert, M. T., Myers, L. L., Duffy, S. A., Bradford, C. R., Chepeha, D. B., Hogikyan, N. D., Prince, M. E., Teknos, T. N., & Wolf, G. T. 2004b, "Disability in patients with head and neck cancer", *Arch.Otolaryngol.Head Neck Surg.*, vol. 130, no. 6, pp. 764-769.

Terrel, J. E., Ronis, D. L., Fowler, K. E., Bradford, C. R., Chepeha, D. B., Prince, M. E., Teknos, T. N., Wolf, G. T., & Duffy, S. A. 2004, "Clinical predictors of quality of life in patients with head and neck cancer.", *Arch.Otolaryngol.Head Neck Surg.*, vol. 130, pp. 401-408.

Thewes, B., Butow, P., Girgis, A., & Pendlebury, S. The psychosocial needs of breast cancer survivors; a qualitative study of the shared and unique needs of younger versus older survivors. Psycho-oncology 13[3], 177-189. 2004.
Ref Type: Journal (Full)

Thomas, R., Daly, M., Perryman, B., & Stockton, D. 2000, "Forewarned is forearmed--benefits of preparatory information on video cassette for patients receiving chemotherapy or radiotherapy--a randomised controlled trial", *Eur J Cancer*, vol. 36, no. 12, pp. 1536-1543.

Thomas, T., Robinson, C., Champion, D., McKell, M., & Pell, M. 1998, "Prediction and assessment of the severity of post-operative pain and of satisfaction with management", *Pain*, vol. 75, no. 2-3, pp. 177-185.

Thompson, A. & Kent, G. 2001, "adjusting to disfigurement: processes involved in dealing with being visibly different", *Clin Psychol Rev.*, vol. 21, no. 5, pp. 663-682.

Timmermans, D., Molewijk, B., Stiggelbout, A., & Kievit, J. 2004, "Different formats for communicating surgical risks to patients and the effect on choice of treatment", *Patient Education and Counseling*, vol. 54, pp. 255-263.

Treacy, J. T. & Mayer, D. K. 2000, "Perspectives on cancer patient education", *Semin.Oncol.Nurs*, vol. 16 , no. 1, pp. 47-56.

True, G., Phipps, E. J., Braitman, L. E., Harralson, T., Harris, D., & Tester, W. Treatment preferences and advance care planning at end of life: the role of ethnicity and spiritual coping in cancer patients. Ann Behav Med 30[2], 174-179. 2005.
Ref Type: Journal (Full)

van balen, F. & Verdurmen, J. 1999, "medical anxiety and the choice for treatment: the development of an instrument to measure fear of treatment", *psychology and health*, vol. 14, pp. 927-935.

van den Brink-Muinen, A. 2002, "The role of genderin healthcare communication", *Patient Education and Counseling* no. 48, pp. 199-200.

Van Der Molen, B. 1999, "Relating information needs to the cancer experiaence: 1.Information as a key coping strategy", *European Journal of Cancer Care*, vol. 8, pp. 238-244.

van Vliet, M. J., Grypdonck, M., van Zuuren, F. J., Winnubst, J. A., & Kruitwagen, C. Preparing patients for gastrointestinal endoscopy: the influence of information in medical situation. Patient Education and Counseling 52[1], 23-30. 2004.
Ref Type: Journal (Full)

van Wilgen, C. P., Dijkstra, P. U., van der Lann, B. F., Plunkker, J. T., & Roodenburg, J. L. Shoulder and neck morbidity in quality of life after surgery for head and neck cancer. Head & Neck 26[10], 839-844. 2004.
Ref Type: Journal (Full)

Vickery, L. E., Latchford, G., Hicken, B., Hewison, J., Bellew, M., & Feber, T. 2003, "The impact of head and neck cancer and facial disfigurement on the quality of life of patients and their partners", *Head & Neck*, vol. 25, no. 4, pp. 289-296.

von Plessen, C. & Aslaksen, A. Improving the quality of palliative care for ambulatory patients with lung cancer. BMJ 330, 1309-1313. 2005.
Ref Type: Journal (Full)

Walker, M. S., Ristvedt, S. L., & Haughey, B. H. 2003, "Patient care in multidisciplinary cancer clinics: Does attention to psychosocial needs predict patient satisfaction?", *Psycho-oncology*, vol. 12, pp. 291-300.

Walter, F. M., Emery, J. D., Rogers, M., & Britten, N. 2004, "Women's views of optimal risk communication and decision making in general practice consultations about the menopause and hormone replacement therapy", *Patient Education and Counseling*, vol. 53, pp. 121-128.

Wan, G. J., Counte, M. A., & Cella, D. F. 1997, "The influence of personal expectations on cancer patients' reports of health-related quality of life", *Psychooncology.*, vol. 6, no. 1, pp. 1-11.

Weis, J. 2003, "Support groups for cancer patients", *Support Care Cancer*, vol. 11, no. 12, pp. 763-768.

Whelan, T., Mohide, E., Willan, A., Arnold, A., Tew, M., Sellick, S., Gafni, A., & Levine, M. The supportive care needs of newly diagnosed cancer patients attending a regional cancer center. Cancer 80, 1518-1524. 1997.
Ref Type: Journal (Full)

Wittchen, H. U. 2000, "The many faces of social anxiety disorder", *Int Clin Psychopharmacol*, vol. 15, no. 1s, pp. 7-12.

Wolf, L. 2004a, "The information needs for women who have undergone breast reconstruction. Part I: decision-making and source of information", *European Journal of Oncology Nursing*, vol. 8, pp. 211-223.

Wolf, L. 2004b, "The information needs for women who have undergone breast reconstruction. Part II: Information giving and content of information", *European Journal of Oncology Nursing*, vol. 8, pp. 315-324.

Woolley, E., Magennis, P., Shokar, P., Lowe, D., Edwards, D., & Rogers, S. N. The correlation between indices of deprivation and health-related quality of life in patients with oral and pharyngeal squamous cell carcinoma. Br.J Oral Maxillofac.Surg. 2005.
Ref Type: Journal (Full)

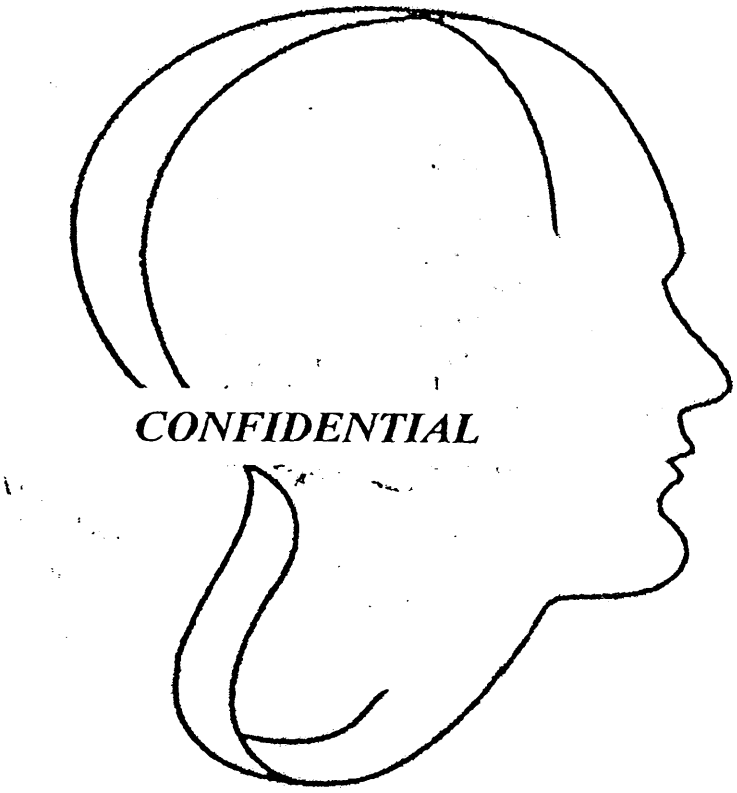
Yu, C. L. M., Fielding, R., & Chan, C. L. W. The mediating role of optimism on post-radiation quality of life in nasopharyngeal carcinoma. Qual.Life Res. 12, 41-51. 2003.
Ref Type: Journal (Full)

Yu, C. L. M., Fielding, R., Chan, C. L. W., & Sham, J. S. Chinese nasopharyngeal carcinoma patients treated with radiotherapy: association between satisfaction with information provided and quality of life. Cancer 92, 2126-2135. 2001.
Ref Type: Journal (Full)

Zigmond, A. S. & Snaith, R. P. The Hospital Anxiety and Depression Scale. Acta Psychiatr Scand 67, 361-370. 1983.
Ref Type: Journal (Full)

Appendix I

Information Needs for Patients with Oral Disease



We are trying to find out if the information received about your oral condition is useful to you.

We would be most grateful if you would give an answer to the following short questions.

UCL

Background information

- Name
- Hospital No.
- Sex [M] [F]
- Age:
- Education:
- Occupation:
- Religion
- Ethnic origin:
- Marital status:
- Postcode:

A) Please state whether the following topics have been explained to you before the start of your treatment in the department of Oral Medicine:

1. What your mouth disease is? yes / no / not sure
2. The possible cause of your mouth disease. yes / no / not sure
3. The kind of the examinations you need. yes / no / not sure
4. The treatment you required? yes / no / not sure
5. Who is going to treat you? yes / no / not sure
6. Where you are going to be treated? yes / no / not sure
7. The possible complications of your treatment yes / no / not sure
8. The likely outcome of your condition yes / no / not sure
9. The effects of the treatment upon your feeling and mood yes / no / not sure
10. Details of patient support groups yes / no / not sure

B) During the planning of your treatment

1. Were you given enough information on possible treatment choices? yes / no / not sure
2. Did you understand the information provided to you? yes / no / not sure
3. Were you able to make choices about your treatment? yes / no / not sure
4. Was the information provided to you correct? yes / no / not sure

C) Please give a score for each clinician you believe was most effective in providing you with the information that you wanted about your condition.
[1= best , 2= average , 3= worst]

☐ 1-Your specialist consultant

☐ 2-Your dentist

☐ 3-Your doctor

☐ 4-The dental nurse

D) Could the information about your Condition or the Treatment you received have been improved? **Yes / No**

- If yes, what additional information would you have liked?
  - ➢ More additional information on.....

- Please state who you would have liked more information from (it can be more than one)

☐ 1-The specialist consultant ☐ 2-The dentist

☐ 3-The doctor ☐ 4-Others.....

F) If we were to provide you with additional relevant information, how would you like this provided to you? (please write a score for each one)

(1 = most preferred.... 5 = least preferred)

Written	1	2	3	4	5
Audio Cassettes	1	2	3	4	5
Video Cassettes	1	2	3	4	5
Personalised computer software	1	2	3	4	5
Internet / World wide web sites	1	2	3	4	5

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE!

Appendix II

CONFIDENTIAL

HAD Scale

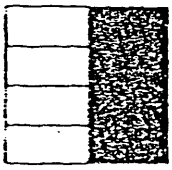
Name

Date

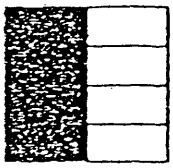
Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he will be abl help you more.
This questionnaire is designed to help your doctor to know how you feel. Read each item and place a firm tick in the box opposite reply which comes closest to how you have been feeling in the past week.
Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-ou response.

Tick only one box in each section

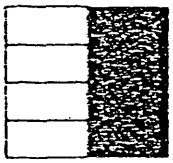
I feel tense or 'wound up':
- Most of the time
- A lot of the time
- Time to time, Occasionally
- Not at all



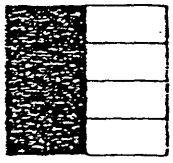
I still enjoy the things I used to enjoy:
- Definitely as much
- Not quite so much
- Only a little
- Hardly at all



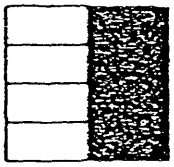
I get a sort of frightened feeling as if something awful is about to happen:
- Very definitely and quite badly
- Yes, but not too badly
- A little, but it doesn't worry me
- Not at all



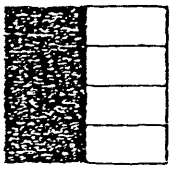
I can laugh and see the funny side of things:
- As much as I always could
- Not quite so much now
- Definitely not so much now
- Not at all



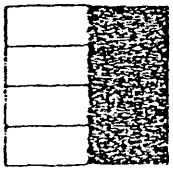
Worrying thoughts go through my mind:
- A great deal of the time
- A lot of the time
- From time to time but not too often
- Only occasionally



I feel cheerful:
- Not at all
- Not often
- Sometimes
- Most of the time

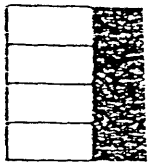


I can sit at ease and feel relaxed:
- Definitely
- Usually
- Not often
- Not at all

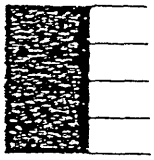


I feel as if I am slowed down:
- Nearly all the time
- Very often
- Sometimes
- Not at all

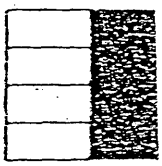
I get a sort of frightened feeling like 'butterflies' in the stomach:
- Not at all
- Occasionally
- Quite often
- Very often



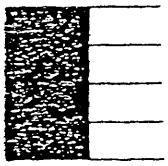
I have lost interest in my appearance:
- Definitely
- I don't take so much care as I should
- I may not take quite as much care
- I take just as much care as ever



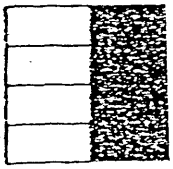
I feel restless as if I have to be on the move:
- Very much indeed
- Quite a lot
- Not very much
- Not at all



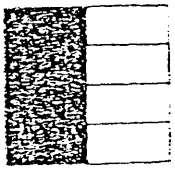
I look forward with enjoyment to things:
- As much as ever I did
- Rather less than I used to
- Definitely less than I used to
- Hardly at all



I get sudden feelings of panic:
- Very often indeed
- Quite often
- Not very often
- Not at all



I can enjoy a good book or radio or TV programme:
- Often
- Sometimes
- Not often
- Very seldom



THE SHORT FORM 36 HEALTH SURVEY QUESTIONNAIRE (SF-36™)

The following questions ask for your views about your health, how you feel and how well you are able to do your usual activities. If you are unsure about how to answer any questions please give the best answer you can and make any of your own comments if you like. Do not spend too much time in answering as your immediate response is likely to be the most accurate.

1. **In general, would you say your health is:**

(Please tick one box)

- Excellent ☐
- Very good ☐
- Good ☐
- Fair ☐
- Poor ☐

2. **Compared to one year ago, how would you rate your health in general now?**

(Please tick one box)

- Much better than one year ago ☐
- Somewhat better than one year ago ☐
- About the same ☐
- Somewhat worse now than one year ago ☐
- Much worse now than one year ago ☐

3. **HEALTH AND DAILY ACTIVITIES**

The following questions are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much?

(Please tick one box on each line)

		Yes, limited a lot	Yes, limited a little	No, not limited at all
a)	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b)	Moderate activities, such as moving a table, pushing a vacuum, bowling or playing golf	☐	☐	☐
c)	Lifting or carrying groceries	☐	☐	☐
d)	Climbing several flights of stairs	☐	☐	☐
e)	Climbing one flight of stairs	☐	☐	☐
f)	Bending, kneeling or stooping	☐	☐	☐
g)	Walking more than a mile	☐	☐	☐
h)	Walking half a mile	☐	☐	☐
i)	Walking 100 yards	☐	☐	☐
j)	Bathing and dressing yourself	☐	☐	☐

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(Please answer Yes or No to each question)

		Yes	No
a)	Cut down on the amount of time you spent on work or other activities	☐	☐
b)	Accomplished less than you would like	☐	☐
c)	Were limited in the kind of work or other activities	☐	☐
d)	Had difficulty performing the work or other activities (eg it took more effort)	☐	☐

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(Please answer Yes or No to each question)

		Yes	No
a)	Cut down on the amount of time you spent on work or other activities	☐	☐
b)	Accomplished less than you would like	☐	☐
c)	Didn't do work or other activities as carefully as usual	☐	☐

6. During the past 4 weeks, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

(Please tick one box)

- Not at all ☐
- Slightly ☐
- Moderately ☐
- Quite a bit ☐
- Extremely ☐

7. How much bodily pain have you had during the past 4 weeks?

(Please tick one box)

- None ☐
- Very mild ☐
- Mild ☐
- Moderate ☐
- Severe ☐
- Very Severe ☐

8. During the past 4 weeks how much did pain interfere with your normal work (including work both outside the home and housework)?

(Please tick one box)

- Not at all ☐
- A little bit ☐
- Moderately ☐
- Quite a bit ☐
- Extremely ☐

YOUR FEELINGS

9. These questions are about how you feel and how things have been with you during the past month. (For each question, please indicate the one answer that comes closest to the way you have been feeling).

(Please tick one box on each line)

	How much time during the last month:	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a)	Did you feel full of life?	☐	☐	☐	☐	☐	☐
b)	Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c)	Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d)	Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e)	Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f)	Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g)	Did you feel worn out?	☐	☐	☐	☐	☐	☐
h)	Have you been a happy person?	☐	☐	☐	☐	☐	☐
i)	Did you feel tired?	☐	☐	☐	☐	☐	☐
j)	Has your health limited your social activities (like visiting friends or close relatives)?	☐	☐	☐	☐	☐	☐

HEALTH IN GENERAL

10. Please choose the answer that best describes how true or false each of the following statements is for you.

(Please tick one box on each line)

		Definitely true	Mostly true	Not sure	Mostly false	Definitely false
a)	I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b)	I am as healthy as anybody I know	☐	☐	☐	☐	☐
c)	I expect my health to get worse	☐	☐	☐	☐	☐
d)	My health is excellent	☐	☐	☐	☐	☐

CONFIDENTIAL

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials: |_|_|_|_|

Your birthdate (Day, Month, Year): |_|_|_|_|_|_|_|_|

Today's date (Day, Month, Year): 31 |_|_|_|_|_|_|_|_|

		Not at All	A Little	Quite a Bit	Very Much
1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2.	Do you have any trouble taking a long walk?	1	2	3	4
3.	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4.	Do you need to stay in bed or a chair during the day?	1	2	3	4
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:		Not at All	A Little	Quite a Bit	Very Much
6.	Were you limited in doing either your work or other daily activities?	1	2	3	4
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8.	Were you short of breath?	1	2	3	4
9.	Have you had pain?	1	2	3	4
10.	Did you need to rest?	1	2	3	4
11.	Have you had trouble sleeping?	1	2	3	4
12.	Have you felt weak?	1	2	3	4
13.	Have you lacked appetite?	1	2	3	4
14.	Have you felt nauseated?	1	2	3	4
15.	Have you vomited?	1	2	3	4

During the past week:	Not at All	A Little	Quite a Bit	Very Much
16. Have you been constipated?	1	2	3	4
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall <u>health</u> during the past week?

1 2 3 4 5 6 7

Very poor Excellent

30. How would you rate your overall <u>quality of life</u> during the past week?

1 2 3 4 5 6 7

Very poor Excellent

EORTC QLQ - H&N35

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:		Not at all	A little	Quite a bit	Very much
31.	Have you had pain in your mouth?	1	2	3	4
32.	Have you had pain in your jaw?	1	2	3	4
33.	Have you had soreness in your mouth?	1	2	3	4
34.	Have you had a painful throat?	1	2	3	4
35.	Have you had problems swallowing liquids?	1	2	3	4
36.	Have you had problems swallowing pureed food?	1	2	3	4
37.	Have you had problems swallowing solid food?	1	2	3	4
38.	Have you choked when swallowing?	1	2	3	4
39.	Have you had problems with your teeth?	1	2	3	4
40.	Have you had problems opening your mouth wide?	1	2	3	4
41.	Have you had a dry mouth?	1	2	3	4
42.	Have you had sticky saliva?	1	2	3	4
43.	Have you had problems with your sense of smell?	1	2	3	4
44.	Have you had problems with your sense of taste?	1	2	3	4
45.	Have you coughed?	1	2	3	4
46.	Have you been hoarse?	1	2	3	4
47.	Have you felt ill?	1	2	3	4
48.	Has your appearance bothered you?	1	2	3	4

Please go on to the next page

During the past week:		Not at all	A little	Quite a bit	Very much
49.	Have you had trouble eating ?	1	2	3	4
50.	Have you had trouble eating in front of your family?	1	2	3	4
51.	Have you had trouble eating in front of other people?	1	2	3	4
52.	Have you had trouble enjoying your meals?	1	2	3	4
53.	Have you had trouble talking to other people?	1	2	3	4
54.	Have you had trouble talking on the telephone?	1	2	3	4
55.	Have you had trouble having social contact with your family?	1	2	3	4
56.	Have you had trouble having social contact with friends?	1	2	3	4
57.	Have you had trouble going out in public?	1	2	3	4
58.	Have you had trouble having physical contact with family or friends?	1	2	3	4
59.	Have you felt less interest in sex?	1	2	3	4
60.	Have you felt less sexual enjoyment?	1	2	3	4

During the past week:		No	Yes
61.	Have you used pain-killers?	1	2
62.	Have you taken any nutritional supplements (excluding vitamins)?	1	2
63.	Have you used a feeding tube?	1	2
64.	Have you lost weight?	1	2
65.	Have you gained weight?	1	2

Appendix III

Educational intervention for oral cancer patients

Study protocol

The potential power of information in stimulating the patients and the public to seek protective health service cannot be underestimated. Cancer prevention and early detection depends largely on changing attitude and behaviours that place people at greater risk. The late presentation of the cancer is a major factor in the high mortality rate, yet chances of survival are better when cancer is detected early.[1,2,21]

The high prevalence of psychological morbidity after head and neck surgery is well documented due to the physically disfiguring treatment and the high mortality rate.[3,4] Despite technical advances in the management of oral and oro-pharyngeal cancer, and the increased number of survivors, there is still a fear accompanying a diagnosis of cancer, of death, pain, loss of independence or attractiveness, and the suffering associated with progressive illness.[3,23]

It has been reported by cancer patients that simple educational and counselling strategies can successfully help to reduce anxiety and psychological distress and actively promote an improvement in subsequent behaviour.[5, 6, 23] Cancer patients wanted as much information as possible.[19] They wanted information related to diagnosis, treatment, medications, side effects, recovery, self-care needs, and effects on work and relationships,[7] with minimal complications.[9, 11]

Effective communication during a consultation may influence patient management in many directions, including the range and number of symptoms disclosed, permits a more precise assessment of the outcome of therapy, co-operation with treatment instructions, impact on emotional and physical well-being, and contributes to both patient and healthcare satisfactions.[24] Inadequate information about the diagnosis, prognosis and therapeutic options can increase anxiety and uncertainty and can lead to dissatisfaction with healthcare in general.[22, 24]

The clinicians' ability to transfer key information to their patients is positively and significantly associated with both patient satisfaction measures and Quality of Life.[14, 15]

There is a growing evidence that patients informed by their physicians are more satisfied with their care.[13] However, to insure that patients receive adequate, digestible and memorable amounts of information during the limited short consultation time, clinicians use supplementary give-away patient's information materials.

Written materials may not be the only desirable mode of delivering information.[7, 8] Well-designed patient's information material in the form of audiotapes and videocassettes were

clinically tested and regarded as a useful additional information strategy within routine oncology practice.[10, 11]

Interactive multimedia computer programs appear to be acceptable and an efficient learning method to facilitate information transfer to patients.[18] Computer programs have several advantages over the traditional leaflet-based information. They can be updated and customised; photographs, diagrams, and other visual images may be used. Furthermore, there is ability to incorporate sound, video-clips, animations, language translation, a list of frequently asked questions (FAQ) can be included with the answers; and following the initial capital outlay, little cost is needed in maintaining and updating the system.

These counselling programs were considered superior to the traditional leaflet-based approach for breast cancer patients.[20] However, patients preferred computer systems that provided information tailored to their situation, not just general information.[12]

Younger, broadsheet readers with previous computer use were more likely to find the multimedia computer system easy to use. More effort should be made to provide effective education for older, less health literate and technologically less literate patients in suitable locations.[7, 16]

Hypothesis: The more detailed information given to the patient preoperatively the more likely the patient will have less anxiety and better quality of life postoperatively.

Aims: The purpose of this study is to:

A) Evaluate the patient preference for information.
B) Evaluate patient's satisfaction with information.
C) Develop and test an interactive multimedia program for use by the oncology nurse and the patients afterward.
D) Evaluate the effect of the intervention by this educational material on the patient's anxiety, knowledge, satisfaction and overall quality of life.

Methods and materials

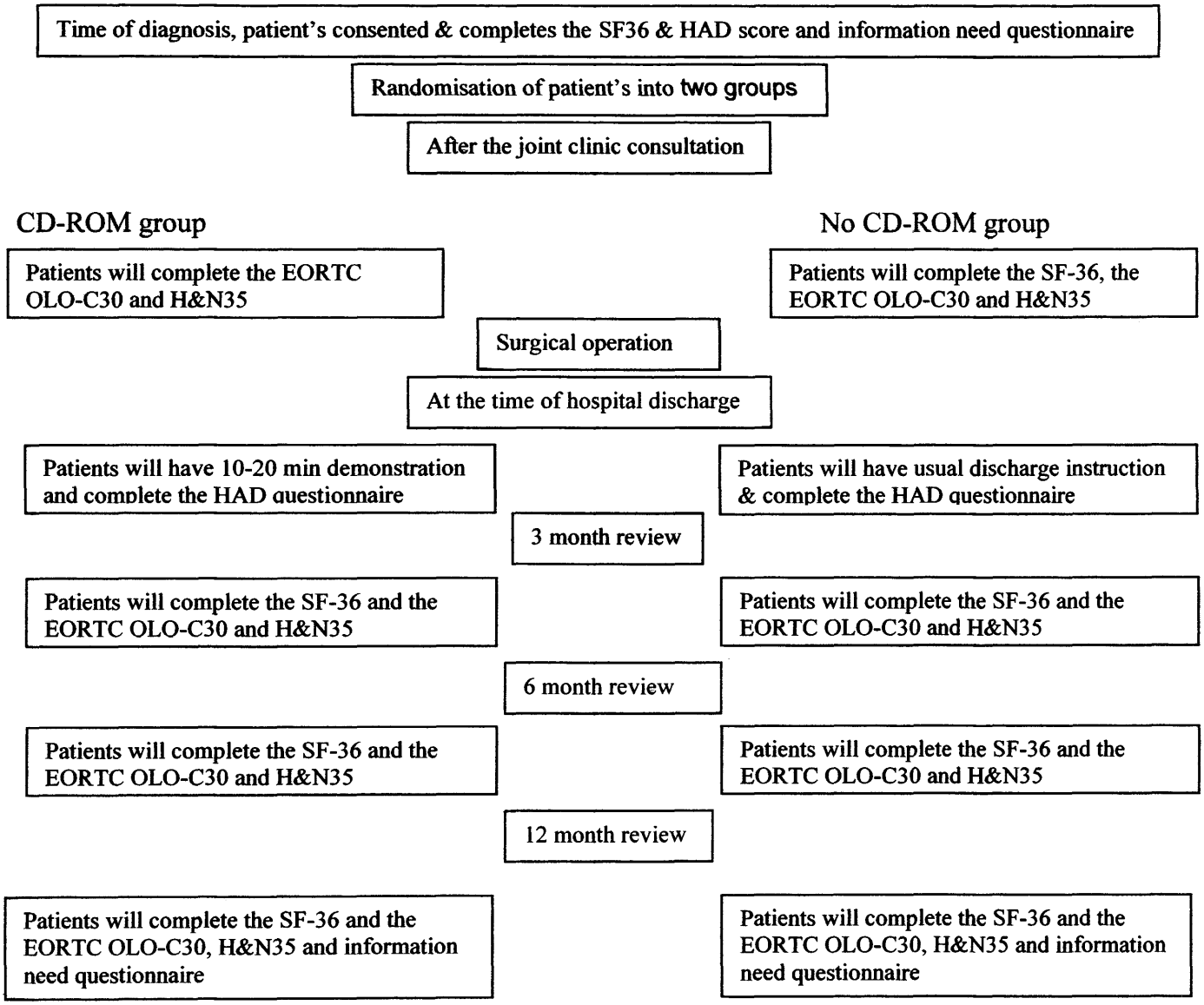
This study will be conducted in two stages:

Stage I: this is a pilot study to explore the patient's satisfaction and preference for information, the form they prefer to see additional information materials and the role this additional information play in informing patients. The study will be a correlational, cross-sectional design on oral and oro-pharyngeal cancer patients' undergone surgery for the treatment of their disease attending the Maxillofacial Unit at the Middlesex Hospital. A self-reported locally developed questionnaire for the information needed and satisfaction will be completed during a short interview between the researcher and the patients attending the unit after a verbal agreement obtained. Descriptive statistical analysis will be mainly through the

use of histograms, and tables of summary statistics. Information preferences and satisfaction will be sorted by correlation/regression analysis.

Stage II: This is a prospective longitudinal randomized controlled clinical trial. Consecutive patients undergoing surgery for previously untreated oral & oro-pharyngeal squamous cell carcinoma attending the Maxillofacial Unit at the Middlesex Hospital will be recruited to the study. The study design is quasi-experimental design (i.e. a type of intervention study that provides comparison but lacks the degree of control on randomisation found in true experiments). The study will be explained to the patients briefly and consent will be obtained thereafter. Patients then will complete a set of questionnaires, the Medical Outcome Study SF-36 (Stewart and Ware 1992)[25] for general well being and HAD (Zigmond and Snaith 1983)[26] for anxiety and depression, at the time of diagnosis. This pre-test will also protect against selective subject loss. Each patient will be allocated thereafter to one of two groups randomly. With the help of the department oncology nurse, patients will be given sealed envelop contains information package. One package will have the information booklet and the multimedia program CD-ROM (group A), the other will have the information booklet only (group B). Group A will receive a 10-20 min demonstration by the oncology nurse on how to use the CD-ROM . The program will contain information to the patient on various subjects including the head and neck cancer and its management; side effects and complications; prognosis and recovery; hospital administrative and investigation procedures; and frequently asked questions by the patients with access to its answers. Group B will receive only the usual information booklet produced by the unit. At the time of the treatment plan decision (the joint clinic) patients in both groups will be asked blindly by the researcher to complete another set of quality of life questionnaires, the cancer core questionnaire EORTC QOL-C30 and the site specific questionnaire H&N35 (K. Bjordal et al, 2000)[27] .At the time of hospital discharge group A will have another 10-20 min demonstration by the oncology nurse on the postoperative part of the CD-ROM, then both groups will complete the postoperative questionnaires (SF-36, EORTC QOL-C30 and H&N35). Patients in the two groups will complete the same postoperative questionnaires at 3 months, 6 months, and 12 months follow-up period. Patients will be asked to complete the questionnaires in a quite place in the clinic before they leave the hospital and assistance will be available whenever needed. The data will be summarised using descriptive statistics, reporting means and intervals with confidence intervals. The null hypothesis will be tested between different groups; and parametric and non-parametric tests will be use in the analysis of the results.

Flow Chart: II Stage



References

- *Br J Oral Maxillofac Surg* 1999 Jun;37(3):181-6. Micrometastasis in oral/oropharyngeal squamous cell carcinoma: incidence, histopathological features and clinical implications. Woolgar JA

- *Laryngoscope* 1994 Oct;104(10):1199-205. Distant metastases from head and neck squamous cell carcinomas. Calhoun KH, Fulmer P, Weiss R, Hokanson JA

- *Otolaryngology-Head and Neck Surgery* 1999 March; 120(3): 427-436. Physical and psychological correlates of head and neck cancer: A review of the literature. Maarten F. De Boer, Laura K. McCormick, Jean F. A. Pruyn, Richard M. Ryckman, and Van Den Borne

- *Oral Oncology* 35 (1999) 27-32. A prospective study on quality of life of patients with cancer of oral cavity or oropharynx treated with surgery with or without radiotherapy. A. de Graeff, J.R.J. de Leeuw, W.J.G. Ros, G.J. Hordijk, G.H. Blijham, J.A.M. Winnubst

- *BMJ* 1990; 301: 575-580. Psychological outcomes of different treatment policies in women with early breast cancer outside a clinical trial. Fallowfield LJ, Hall A, Maguire GP, Baum M.

- *Cancer Nurs* 1995 Jun;18(3):206-14. The effect of preparatory patient education on the anxiety and satisfaction of cancer patients receiving radiation therapy. Poroch D.

- *Semin Oncol Nurs* 2000 Feb;16(1):47-56. Perspectives on cancer patient education. Treacy JT, Mayer DK.

- *Oncol Nurs Forum* 1995 Oct;22(9):1345-51. Patient literacy and the readability of written cancer educational materials. Cooley ME, Moriarty H, Berger MS, Selm-Orr D, Coyle B, Short T.

- *J Clin Oncol* 1993 Nov;11(11):2279-85. General information tapes inhibit recall of the cancer consultation. Dunn SM, Butow PN, Tattersall MH, Jones QJ, Sheldon JS, Taylor JJ, Sumich MD.

- *Oncol Nurs Forum* 1996 May;23(4):697-700. The effects of informational audiotapes on knowledge and self-care behaviors of patients undergoing radiation therapy. Hagopian GA.

- *Eur J Cancer* 2000 Aug;36(12):1536-43. Forewarned is forearmed--benefits of preparatory information on video cassette for patients receiving chemotherapy or radiotherapy--a randomised controlled trial. Thomas R, Daly M, Perryman B, Stockton D

- *BMJ* 1999 Nov 6;319(7219):1241-7. Randomised trial of personalised computer based information for cancer patients. Jones R, Pearson J, McGregor S, Cawsey AJ, Barrett A, Craig N, Atkinson JM, Gilmour WH, McEwen J.

- *J Fam Pract* 2000 Apr;49(4):314-8. The physician's role in educating patients. A comparison of mailed versus physician-delivered patient education. Terry PE, Healey ML.

- *Int J Qual Health Care* 1996 Oct;8(5):447-56. The relationship between meeting patients' information needs and their satisfaction with hospital care and general health status outcomes. Larson CO, Nelson EC, Gustafson D, Batalden PB.

- *Tumori* 1998 Nov-Dec;84(6):619-23. Does the information level of cancer patients correlate with quality of life? A prospective study. Annunziata MA, Foladore S, Magri MD, Crivellari D, Feltrin A, Bidoli E, Veronesi A.

- *Proc AMIA Symp* 1999;:594-8. The accessibility of information systems for patients: use of touchscreen information systems by 345 patients with cancer in Scotland. Pearson J, Jones R, Cawsey A, McGregor S, Barrett A, Gilmour H, Atkinson J, McEwen J.

- *Soc Sci Med* 2000 Dec;51(12):1817-25. Information and its impact on satisfaction among surgical patients. Krupat E, Fancey M, Cleary PD.

- *Cancer Pract* 1996 Nov-Dec;4(6):341-5. Results of a patient education project using a touch-screen computer. Fieler VK, Borch A

- *BMJ* 1999; 319:1247-1248. Cross sectional survey of patients' satisfaction with information about cancer. Ray Jones, Janne Pearson, Sandra McGregor, W Harper Gilmour, Jacqueline M Atkinson, Ann Barrett, Alison J Cawsey, Jim McEwen,

- *European Journal of Surgical Oncology* 1998; 24: 496-498. Interactive multimedia information program for use by breast-care nurses – a patient acceptability study. E. Street, P.J. Carlton, J.R.T. Monson, J.N. Fox, G.S. Duthie and M.J. Kerin

- *Community Dental Health* 1993; 10(1): 87-89. Conclusions and recommendations of the U.K. working group on screening for oral cancer and precancer.

- *European Journal of Cancer* 1999; 35(11): 1587-1591. Cancer information: a cost-effective intervention. Mossman J, Boudioni M, Slevin ML.

- *European Journal of Cancer* 1999; 35(11): 1559-1564. Psychological intervention for patients with cancer: what works and what doesn't. F.I. Fawzy

- *European Journal of Cancer* 1999; 35(11): 1592-1597. Effective communication skills are the key to good cancer care. L. Fallowfield and V. Jenkins

- Ware, J.E. (1992). Measures for a new era of health assessment. In: A.L. Stewart and J.E. Ware (eds), *Measuring Functioning and Well-being: The Medical Outcomes Study Approach.* Durham, NC: Duke University Press

- *Acta Psychiatr Scand* 1983; 67: 361-370. The Hospital Anxiety and Depression Scale. Zigmond AS, Snaith RP

- *Eur J Cancer* 2000 Sep;36(14):1796-807. A 12 country field study of the EORTC QLQ-C30 (version 3.0) and the head and neck cancer specific module (EORTC QLQ-H&N35) in head and neck patients. EORTC Quality of Life Group. Bjordal K, de Graeff A, Fayers PM, Hammerlid E, van Pottelsberghe C, Curran D, Ahlner-Elmqvist M, Maher EJ, Meyza JW, Bredart A, Soderholm AL, Arraras JJ, Feine JS, Abendstein H, Morton RP, Pignon T, Huguenin P, Bottomly A, Kaasa S.

INFORMATION SHEET

Educational intervention for oral and pharyngeal cancer patients

Most patients found to have cancer are capable to cope and adjust to changes in their life due to the disease or its treatment. However some may have psychological upset, which in future may adversely affect their quality of life. The overall aim of the present study is to seek method of identifying the patient's who have become disturbed following the diagnosis and treatment of oral and pharyngeal cancer, and develop method of providing information to reassure such individuals.

The research is based on information collected by a set of questionnaires to be completed by the patient at the time of diagnosis. Patient will be asked to complete a series of questionnaires during their follow-up appointments at the clinic. Completing the forms will require approximately 20-30 min; assistance will be available on request.

Access to the results will be restricted and confidential. You do not have to take part of this study if you do not want to. If you decide to take part you may withdraw at any time without having to give a reason. Your decision whether to take part or not will not affect your care and management in any way. The joint UCL/UCLH committee on the Ethics of Human Research have approved this study.

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Consent Form

Educational intervention in the management of oral and oro-pharyngeal cancer

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Prof. Stanton Newman
Mr. Laurence Newman FDSRCS
Mr. Colin Hopper FDSRCS
Dr. Sami Sowairi MSc

Department of Oral and Maxillofacial Surgery
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Dr Sajeda Meghji (Ext. 1271)
Mr Lawrence Newman (Tel.: 020-73809859)
Miss Jane Stewart (Ext. 1116), Sec. Julia Panova (Ext. 1148)
Mr Tony Snowdon (Ext. 2307)
Direct Departmental Fax: 020-79151259

Please take a moment to read and answer the following questions:

1. Have you received enough information about this study? Yes/No
2. Have you had the opportunity to ask questions and discuss this study? Yes/No
3. Have you received satisfactory answers to all your questions? Yes/No
4. Which doctor have you spoken to about this study?
   Dr: ***Sami Sowairi***
5. Do you understand that you are free to withdraw from this study
   - At any time Yes/No
   - Without giving a reason for withdrawing Yes/No
   - Without affecting your future medical care Yes/No
6. Do you agree to take part in this study? Yes/No

Signed Date

Name in block letters:

Quality of life in Head and Neck Cancer patients

Patient's name: ..... **Hospital No**.....

DOB: ...../...../..... **Gender** M / F **Marital Status** .....

Address: .... **Post code** .....

Type of education:
1- Primary school 2- secondary vocational school

3- Intermediate vocational/ high school 4- Higher vocational school or university

Employment status: 1- Employed 2- Not employed

Family income level: 1- Below modal 2- Modal 3- Above modal

Alcohol abuse: 1- Yes 2- No

Smoking: 1- Yes 2- No

Diagnosis: ..... **Date:** ...../...../.....

Tumour site 1- Lip Cheek 2- Hard palate 3- Floor of mouth 4- Anterior 2/3 tongue
5- Soft palate 6- Retromolar pad 7- Alveolar 8- Tongue base 9- Other

Clinical stage (TNM) ..... **Recurrence** Yes No

Stage of Treatment: 1) Preoperative 2) $\leq$ 3 months 3) $\leq$ 1 year 4) > 1 year

Surgery: A- Bone: 1- no or rim resection 2- Segment resection

B- Soft tissue: 1- Anterior / Lateral 2- Posterior / Medial

C- Neck dissection: 1- I-III 2- IV-V

D- Reconstruction: 0- Non vascular flap 2- Vascular flap

Radiotherapy: .....

Chemotherapy: .....

Appendix IV

Table 2.4.1.3: HADS preoperative scores

		anxiety		depression	
	HADS score	<8 (%)	8+ (%)	<8 (%)	8+ (%)
Patients age	<60 years	3 (30)	7 (70)	6 (60)	4 (40)
	≥60 years	5 (56)	4 (44)	8 (89)	1 (11)
Patients gender	Male	6 (50)	6 (50)	7 (58)	5 (42)
	Female	2 (29)	5 (71)	7(100)	0
Marital status	Married	2 (25)	6 (75)	7 (88)	1 (12)
	Single	5 (56)	4 (44)	6 (67)	3 (33)
Tumour size	T1 & T2	3 (75)	1 (25)	4(100)	0
	T3 & T4	3 (25)	9 (75)	8 (67)	4 (33)

Table 2.4.1.4: HADS scores at 3-months stage

		anxiety		depression	
	HADS score	<8 (%)	8+ (%)	<8 (%)	8+ (%)
Patients age	<60 years	2 (25)	6 (75)	5 (63)	3 (37)
	≥60 years	2	0	2	0
Patients gender	Female	2 (50)	2 (50)	3 (75)	1 (25)
	Male	2 (33)	4 (67)	4 (67)	2 (33)
Marital status	Single	1 (25)	3 (75)	3 (75)	1 (25)
	Married	2 (40)	3 (60)	3 (60)	2 (40)
Tumour size	T1 & T2	1 (25)	3 (75)	3 (75)	1 (25)
	T3 & T4	2 (40)	3 (60)	3 (60)	2 (40)
Bone resection	No or marginal	3 (37)	5 (63)	6 (75)	2 (25)
	Complete	1 (50)	1 (50)	1 (50)	1 (50)
Relation of soft tissue resection to teeth	Ant. or lat.	2 (67)	1 (33)	2 (67)	1 (33)
	Post. or med.	2 (29)	5 (71)	5 (71)	2 (29)
Neck dissection	I-III	3 (50)	3 (50)	5 (83)	1 (17)
	IV-V	1 (25)	3 (75)	2 (50)	2 (50)
Reconstruction	Non vascular	1	0	1	0
	Vascular flap	3 (33)	6 (67)	6 (67)	3 (33)
Radiotherapy	No	2 (33)	4 (67)	4 (67)	2 (33)
	Yes	2 (50)	2 (50)	3 (75)	1 (25)

Table 2.4.1.5: HADS scores at 6-months stage

		anxiety		depression	
		<8 (%)	8+ (%)	<8 (%)	8+ (%)
Patients age	<60 years	5 (63)	3 (37)	6 (75)	2 (25)
	≥60 years	4 (45)	5 (55)	7 (78)	2 (22)
Patients gender	Female	2 (40)	3 (60)	5(100)	0
	Male	7 (58)	5 (42)	8 (67)	4 (33)
Marital status	Single	3 (38)	5 (62)	6 (75)	2 (25)
	Married	6 (67)	3 (33)	7 (78)	2 (22)
Tumour size	T1 & T2	4 (58)	3 (42)	6 (86)	1 (14)
	T3 & T4	5 (50)	5 (50)	7 (70)	3 (30)
Bone resection	No or marginal	6 (43)	8 (57)	11 (79)	3 (21)
	Complete	3(100)	0	2 (67)	1 (33)
Relation of soft tissue resection to teeth	Ant. or lat.	3(100)	0	3(100)	0
	Post. or med.	6 (43)	8 (57)	10 (71)	4 (29)
Neck dissection	I-III	6 (50)	6 (50)	10 (83)	2 (17)
	IV-V	3 (60)	2 (40)	3 (60)	2 (40)
Reconstruction	Non vascular	1	0	1	0
	Vascular flap	8 (50)	8 (50)	12 (75)	4 (25)
Radiotherapy	No	3 (43)	4 (57)	7(100)	0
	Yes	6 (60)	4 (40)	6 (60)	4 (40)

Table 2.4.1.6: HADS scores at 12-months stage

		anxiety		depression	
		<8 (%)	8+ (%)	<8 (%)	8+ (%)
Patients age	<60 years	2 (40)	3 (60)	3 (60)	2 (40)
	≥60 years	5 (63)	3 (37)	8(100)	0
Patients gender	Female	1 (25)	3 (75)	3 (75)	1 (25)
	Male	6 (67)	3 (33)	8 (89)	1 (11)
Marital status	Single	3 (50)	3 (50)	5 (83)	1 (17)
	Married	2 (40)	3 (60)	4 (80)	1 (20)
Tumour size	T1 & T2	2 (50)	2 (50)	4(100)	0
	T3 & T4	5 (63)	3 (37)	7 (88)	1 (12)
Bone resection	No or marginal	6 (60)	4 (40)	9 (90)	1 (10)
	Complete	1 (33)	2 (67)	2 (67)	1 (33)
Relation of soft tissue resection to teeth	Ant. or lat.	3 (50)	3 (50)	5 (83)	1 (17)
	Post. or med.	4 (57)	3 (43)	6 (86)	1 (14)
Neck dissection	I-III	5 (55)	4 (45)	8 (88)	1 (12)
	IV-V	2 (50)	2 (50)	3 (75)	1 (25)
Reconstruction	Non vascular	1 (50)	1 (50)	2(100)	0
	Vascular flap	6 (54)	5 (46)	9 (82)	2 (18)
Radiotherapy	No	2 (50)	2 (50)	3 (75)	1 (25)
	Yes	5 (56)	4 (44)	8 (88)	1 (12)

Table 2.4.1.7: HADS scores at 24-months stage

		anxiety		depression	
		<8 (%)	8+ (%)	<8 (%)	8+ (%)
Patients age	<60 years	5 (38)	8 (62)	10 (71)	4 (29)
	≥60 years	14 (74)	5 (26)	16 (84)	3 (16)
Patients gender	Female	2 (33)	4 (67)	5 (83)	1 (17)
	Male	17 (63)	10 (37)	21 (78)	6 (22)
Marital status	Single	7 (64)	4 (36)	10 (90)	1 (10)
	Married	10 (53)	9 (47)	13 (68)	6 (32)
Tumour size	T1 & T2	13 (62)	8 (38)	18 (86)	3 (14)
	T3 & T4	5 (50)	5 (50)	6 (60)	4 (40)
Bone resection	No/marginal	16 (59)	11 (41)	23 (85)	4 (15)
	Complete	3 (50)	3 (50)	3 (50)	3 (50)
Relation of soft tissue resection to teeth	Ant./lat.	7 (58)	5 (42)	9 (69)	4 (31)
	Post./med.	12 (57)	9 (43)	17 (85)	3 (15)
Neck dissection	I-III	13 (68)	6 (32)	15 (79)	4 (21)
	IV-V	6 (43)	8 (57)	11 (79)	3 (21)
Flap Reconstruction	Non vascular	8 (62)	5 (38)	11 (85)	2 (15)
	Vascular	11 (55)	9 (45)	15 (75)	5 (25)
Radiotherapy	No	7 (50)	7 (50)	11 (79)	3 (21)
	Yes	12 (63)	7 (37)	15 (79)	4 (21)

Table 2.4.2.3: Summary of longitudinal study patients with caseness for anxiety or depression based on their characteristics

		Preoperative		6-months post.op	
	Anxiety score	<8	8+	<8	8+
Patients age	<60 years	3	2	3	2
	≥60 years	1	3	3	1
Patients gender	Female	0	3	2	1
	Male	4	2	4	2
Marital status	Single	2	3	3	2
	Married	2	2	3	1
Tumour size	T1 & T2	3	0	3	0
	T3 & T4	1	5	3	3
Lymph node involvement	Negative	4	1	4	1
	Positive	0	4	2	2
Bone resection	No or marginal	3	5	5	3
	Complete	1	0	1	0
Relation of soft tissue resection to teeth	Ant. or lat.	1	0	1	0
	Post. or med.	3	5	5	3
Neck dissection	I-III	3	3	4	2
	IV-V	1	2	2	1
Reconstruction	Non vascular	0	1	1	0
	Vascular flap	4	4	5	3
Radiotherapy	No	1	2	2	1
	Yes	3	3	4	2

Appendix V

Table 2.4.1.14: Patients' SF-36 scores at preoperative stage

Preoperative stage			PF	RP	RE	SF	MH	E/V	Pain	GH
Patients age	<60 years	Mean	76.7	36.1	33.3	48.2	46.2	51.6	64.2	55.7
		Median	85	.0	.00	33.3	48	40	66.7	52
	≥60 years	Mean	69.3	64.3	61.9	73	70.3	60	69.8	67.1
		Median	80	100	100	77.8	68	65	77.8	62
Patients gender	Female	Mean	78.6	50	47.6	63.5	62.9	57.1	66.7	70.9
		Median	80	25	33.3	55.6	60	65	77.8	62
	Male	Mean	69.4	47.2	44.4	55.6	52	53.8	66.7	52.8
		Median	80	50	33.3	55.6	52	40	66.7	52
Marital status	Single	Mean	68.6	28.6	28.6	49.2	57.1	59.1	63.5	54.9
		Median	80	.00	.00	44.4	60	60	77.8	52
	Married	Mean	85	67.9	61.9	63.5	53.7	52.1	65.1	69.3
		Median	85	100	100	77.8	56	40	66.7	67
Tumour size	T1 & T2	Mean	91.7			88.9	58.7	66.7	77.8	81.3
		Median	95			88.9	64	75	66.7	77
	T3 & T4	Mean	71.5	35	33.3	51.1	54.8	46	54.4	58.8
		Median	82.5	12.5	16.7	50	54	40	55.6	55
Lymph node involvement	Negative	Mean	81.1	52.8	51.9	61.7	51.1	55.4	67.9	69.2
		Median	85	50	33.3	55.6	48	40	66.7	67
	Positive	Mean	60.8	45.8	44.4	57.4	64.7	53.3	61.1	49.3
		Median	62.5	37.5	33.3	61.1	68	50	61.1	55

Table 2.4.1.15: Patients' SF-36 scores at 3-months stage

			PF	RP	RE	SF	MH	E/V	Pain	GH
Patients Age	<60 years (8)	Mean	70.6	25	41.7	56.9	59	40.6	47.2	60
		Median	77.5	12.5	16.7	55.6	58	45	50	57
	≥60 years (2)	Mean	70		83.3	61.1	82			58.5
		Median	70		83.3	61.1	82			58.5
Patients gender	Female (4)	Mean	55	6.25	50	55.6	59	41.3	63.9	51.8
		Median	56.4	.00	50	61.1	58	45	77.8	45
	Male (6)	Mean	80.8	29.2	50	59.3	66.7	41.7	46.3	65
		Median	87.5	12.5	50	55.6	66	45	50	69.5
Marital Status	Single (4)	Mean	75	25	41.7	55.6	65	36.3	55.6	56
		Median	75	.00	33.3	55.6	66	40	55.6	53.5
	Married (5)	Mean	62	10	46.7	53.3	56.8	42	48.9	57.2
		Median	70	.00	33.3	55.6	52	45	44.4	47
Tumour Size	T1 & T2 (4)	Mean	85	31.3	58.3	58.3	56	31.3	58.3	70.3
		Median	87.5	12.5	66.7	61.1	60	30	55.6	69.5
	T3 & T4 (5)	Mean	54	5	33.3	51.1	64	46	46.7	45.8
		Median	65	.00	.00	55.6	54	45	33.3	45
Lymph node involvement	Negative (6)	Mean	83.3	33.3	55.6	63	61.3	39.2	53.7	69.2
		Median	87.5	25	66.7	61.1	60	45	55.6	69.5
	Positive (4)	Mean	51.3		41.7	50	67	45	52.8	45.5
		Median	60		33.3	50	70	45	55.6	40
Bone Resection	No/ Marginal(8)	Mean	75	18.8	50	56.9	63	37.5	55.6	58.1
		Median	72.5	.00	50	55.6	66	42.5	55.6	57
	Complete (2)	Mean	52.5	25	50	61.1	66	57.5	44.4	66
		Median	52.5	25	50	61.1	66	57.5	44.4	66
Relation of soft tissue resection to teeth	Ant./lat. (3)	Mean	83.3	25	66.7	66.7	72	50	44.4	67
		Median	90	25	100	55.6	72	50	44.4	67
	Post./med. (7)	Mean	65	17.9	42.9	54	60	37.9	57.1	56.6
		Median	70	.00	33.3	55.6	64	45	55.6	45
Neck dissection	I-III (6)	Mean	80.8	25	61.1	61.1	70.7	40.8	55.6	63
		Median	87.5	.00	83.3	61.1	70	42.5	55.6	69
	IV-V (4)	Mean	55	12.5	33.3	52.8	53	42.5	50	54.8
		Median	67.5	12.5	16.7	55.6	46	47.5	50	46
Radiotherapy	No (6)	Mean	79.2	33.3	50	64.8	62	40	59.3	63.8
		Median	77.5	25	50	66.7	60	47	61.1	59.5
	Yes (4)	Mean	57.5		50	47.2	66	43.8	44.4	53.5
		Median	65		50	50	68	42.5	38.9	56

Table 2.4.1.16: Patients' SF-36 scores at 6-months stage

			PF	RP	RE	SF	MH	E/V	Pain	GH
Patients Age	<60 years (8)	Mean	67.6	47.6	58.3	72.2	67.5	55.6	72.2	65.9
		Median	80	40.5	66.7	88.9	64	55	77.8	74.5
	≥60 years (8)	Mean	60	51.6	66.7	76.4	75.5	56.3	72.2	58.4
		Median	70	56.5	83.3	88.9	78	60	83.3	64.5
Patients gender	Female (4)	Mean	70.8	47	58.3	86.1	74	63.8	86.1	65.3
		Median	76.5	44	66.7	88.9	78	65	88.9	72
	Male (12)	Mean	61.3	50.5	63.9	70.4	70.7	53.3	67.6	61.1
		Median	77.5	50	100	88.9	66	55	77.8	67
Marital Status	Single (7)	Mean	60.1	35.7	57.1	68.3	64.6	47.9	73	54.7
		Median	65	.00	66.7	88.9	60	50	77.8	62
	Married (9)	Mean	66.4	60.4	66.7	79	76.9	62.2	71.6	67.9
		Median	85	63	100	88.9	84	65	88.9	72
Tumour Size	T1 & T2 (6)	Mean	78	69.8	72.2	92.6	72.7	62.5	72.2	77
		Median	84	69	100	100	68	62.5	77.8	79.5
	T3 & T4 (10)	Mean	55.1	37.5	56.7	63.3	70.8	52	72.2	53.2
		Median	57.5	12.5	66.7	83.3	74	50	77.8	62
Lymph node involvement	Negative (9)	Mean	69.2	60.4	70.4	84	69.3	57.2	76.5	72.6
		Median	80	63	100	88.9	68	60	77.8	72
	Positive (7)	Mean	56.6	35.7	52.4	61.9	74.3	54.3	66.7	48.7
		Median	65	.00	66.7	77.8	88	55	77.8	40
Bone Resection	No/ Marginal(13)	Mean	61.1	49.5	59	76.9	70	55	69.2	60.2
		Median	75	50	66.7	88.9	68	55	77.8	67
	Complete (3)	Mean	75	50	77.8	63	78.7	60	85.2	70.3
		Median	85	50	100	77.8	92	65	88.9	67
Relation of soft tissue resection to teeth	Ant./lat. (3)	Mean	85	60.3	77.8	88.9	90.7	71.7	70.4	73.7
		Median	85	50	100	88.9	92	65	88.9	72
	Post./med. (13)	Mean	58.7	47.2	59	70.9	67.1	52.3	72.7	59.5
		Median	65	50	66.7	88.9	64	50	77.8	62
Neck dissection	I-III (11)	Mean	63.9	38.1	54.5	71.7	70.6	54.1	68.7	60.1
		Median	80	31	66.7	88.9	68	55	77.8	67
	IV-V (5)	Mean	63.2	75	80	80	73.6	60	80	66.6
		Median	75	100	100	88.9	88	65	77.8	67
Radiotherapy	No (6)	Mean	74.7	56.3	72.2	88.9	71.3	61.7	83.3	70
		Median	84	56.5	83.3	88.9	68	57.5	88.9	79.5
	Yes (10)	Mean	57.1	45.6	56.7	65.6	71.6	52.5	65.6	57.4
		Median	62.5	40.5	66.7	83.3	74	52.5	77.8	64.5

Table 2.4.1.17: Patients' SF-36 scores at 12-months stage

			PF	RP	RE	SF	MH	E/V	Pain	GH
Patients age	<60 years (5)	Mean	72	70	60	57.8	64	48	66.7	53.2
		Median	90	100	100	66.7	68	40	66.7	40
	≥60 years (7)	Mean	60.7	38.4	52.4	73	76	55.7	79.4	57.9
		Median	65	25	66.7	66.7	76	60	77.8	72
Patients gender	Female (4)	Mean	62.5	43.8	75	66.7	65	52.5	58.3	50.3
		Median	67.5	37.5	100	66.7	70	47.5	55.6	41
	Male (8)	Mean	66.9	55.5	45.8	66.6	74	52.5	81.9	58.8
		Median	72.5	72	33.3	66.7	78	62.5	83.3	72
Marital status	Single (6)	Mean	69.2	49	50	66.6	68	59.2	87	70
		Median	77.5	47	50	77.8	72	65	94.4	74.5
	Married (4)	Mean	70	62.5	66.7	66.7	68	46.3	61.1	47.3
		Median	75	75	83.3	66.7	74	37.5	66.7	37.5
Tumour size	T1 & T2 (3)	Mean	65	39.7	66.7	77.8	73.3	70	81.5	68.7
		Median	75	25	100	66.7	72	75	100	77
	T3 & T4 (8)	Mean	66.3	50	45.8	62.4	75	48.1	72.2	53.1
		Median	72.5	50	33.3	66.7	78	50	77.8	53.5
Lymph node involvement	Negative (7)	Mean	72.9	74.1	85.7	84.1	73.1	66.4	84.1	71
		Median	75	100	100	88.9	76	65	88.9	77
	Positive (5)	Mean	55	20	13.3	42.1	68	33	60	34.8
		Median	65	.00	.00	44	72	35	66.7	32
Bone resection	No/ Marginal(9)	Mean	64.4	41	51.9	66.6	75.1	54.4	79	58.6
		Median	75	25	66.7	66.7	80	60	77.8	72
	Complete (3)	Mean	68.3	83.3	66.7	66.7	58.7	46.7	59.3	48
		Median	60	100	100	66.7	68	40	66.7	40
Relation of soft tissue resection to teeth	Ant./lat. (6)	Mean	86.7	74	66.7	75.9	69.3	64.2	79.6	69.2
		Median	92.5	97	100	77.8	70	70	94.4	79.5
	Post./med. (6)	Mean	44.2	29.2	44.4	57.3	72.7	40.8	68.5	42.7
		Median	42.5	12.5	33.3	66.7	78	45	72.2	38.5
Neck dissection	I-III (9)	Mean	72.8	52.1	63	70.3	72.9	57.8	74.1	62.7
		Median	80	50	100	66.7	72	60	77.8	72
	IV-V (3)	Mean	43.3	50	33.3	55.6	65.3	36.7	74.1	35.7
		Median	55	50	.00	66.7	76	35	77.8	20
Flap Reconstruction	Non vascular(2)	Mean	50	12.5		83.3	80	67.5	72.2	64.5
		Median	50	12.5		83.3	80	67.5	72.2	64.5
	Vascular (10)	Mean	68.5	59.4	46.7	63.3	69.2	49.5	74.4	54.2
		Median	72.5	72	33.3	66.7	74	50	77.8	56
Radiotherapy	No (4)	Mean	65	56.3		80.6	71	58.8	77.8	66.5
		Median	67.5	62.5		77.8	80	60	83.3	64.5
	Yes (8)	Mean	65.6	49.3	33.3	59.7	71	49.4	72.2	50.6
		Median	72.5	50	.00	66.7	74	50	77.8	53.5

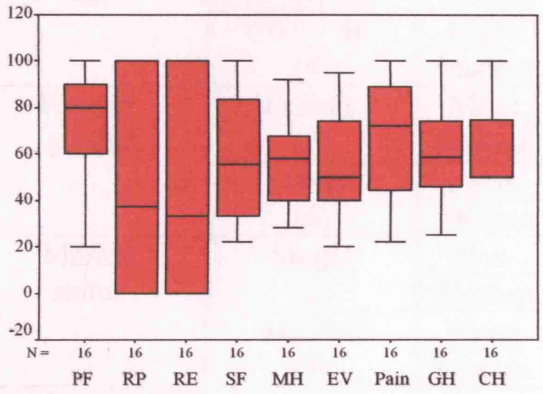
Table 2.4.1.18: Patients' SF-36 scores at 24-months stage

			PF	RP	RE	SF	MH	E/V	Pain	GH
Patients age	<60 years (13)	Mean	80.7	69.2	64.1	71.8	65.6	51.2	70.1	53
		Median	85	75	66.7	77.8	68	50	77.8	47
	≥60 years (15)	Mean	61	40	62.2	63.7	77.9	55.7	64.4	50
		Median	65	25	100	77.8	76	60	66.7	37
Patients gender	Female (5)	Mean	85	60	93.3	88.9	71.2	59	66.7	73.6
		Median	85	50	100	88.9	84	60	66.7	87
	Male (23)	Mean	67	52.2	56.5	62.8	72.5	52.4	67.2	46.6
		Median	75	50	66.7	55.6	76	50	66.7	37
Marital status	Single (11)	Mean	73.6	52.3	63.6	75.8	76.4	59.1	63.6	47.4
		Median	85	50	66.7	88.9	80	60	66.7	35
	Married (15)	Mean	69.3	58.3	71.1	63.7	70.1	51.3	71.1	55.9
		Median	75	100	100	77.8	76	50	88.9	47
Tumour size	T1 & T2 (19)	Mean	72.4	47.4	61.4	66.7	74.1	49.2	62.6	46.7
		Median	85	50	66.7	77.8	76	50	66.7	37
	T3 & T4 (7)	Mean	59.3	57.1	57.1	61.9	71	58.6	69.8	55.4
		Median	75	100	100	44.4	68	55	77.8	42
Lymph node involvement	Negative (20)	Mean	73	58.8	70	74	75.2	55.5	67.2	53.7
		Median	85	62.5	100	88.9	78	50	66.7	46
	Positive (7)	Mean	68.6	46.4	52.4	54	64.6	47.1	71.4	47.3
		Median	75	50	66.7	44.4	68	55	77.8	42
Bone resection	No/ Marginal(24)	Mean	70.2	50	61.1	67.6	74	52.3	64.8	50.1
		Median	85	50	66.7	77.8	76	50	66.7	41
	Complete (4)	Mean	70	75	75	66.7	62	61.3	80.6	59
		Median	75	100	100	66.7	58	65	100	59.5
Relation of soft tissue resection to teeth	Ant./lat. (9)	Mean	76.1	69.4	81.5	77.8	71.6	61.1	71.6	70.4
		Median	85	100	100	88.9	76	70	100	87
	Post./med. (19)	Mean	67.4	46.1	54.4	62.6	72.6	50	64.9	42.4
		Median	75	50	66.7	55.6	76	50	66.7	35
Neck dissection	I-III (15)	Mean	78.7	68.3	75.6	77	78.7	62	70.4	60.7
		Median	85	100	100	88.9	84	60	88.9	72
	IV-V (13)	Mean	60.4	36.5	48.7	56.4	64.9	43.9	63.3	40.6
		Median	75	25	66.7	44.4	68	40	66.7	35
Flap Reconstruction	Non vascular (11)	Mean	74.5	52.3	72.7	65.6	75.3	45	64.7	58.5
		Median	85	50	100	77.8	76	35	66.7	47
	Vascular (17)	Mean	67.4	54.4	56.9	68.6	70.4	59.1	68.6	46.8
		Median	75	50	66.7	88.9	68	60	66.7	35
Radiotherapy	No (12)	Mean	74.1	62.5	75	73.2	68	51.7	69.4	56.2
		Median	85	87.5	100	83.3	68	50	72.2	46
	Yes (16)	Mean	67.2	46.8	54.2	63.2	75.5	55	65.3	47.8
		Median	75	50	66.7	66.7	80	52.5	66.7	38.5

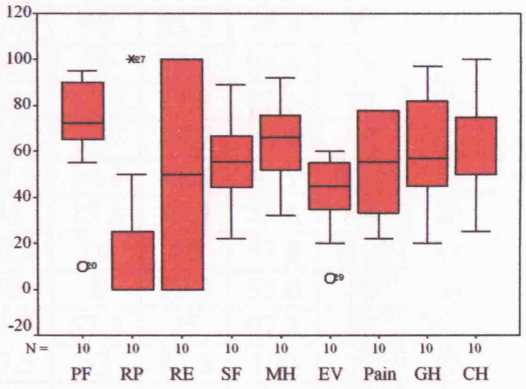
Appendix VI

Plate 1:

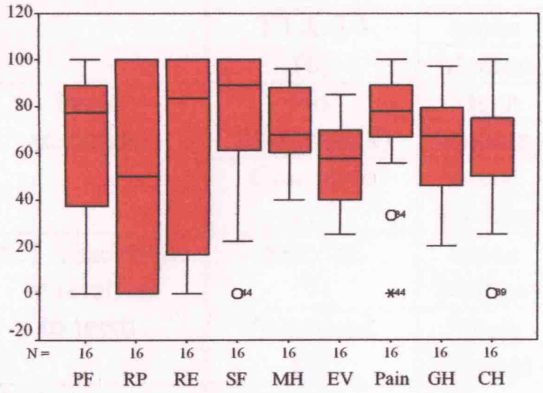
SF-36 scores at preoperative stage



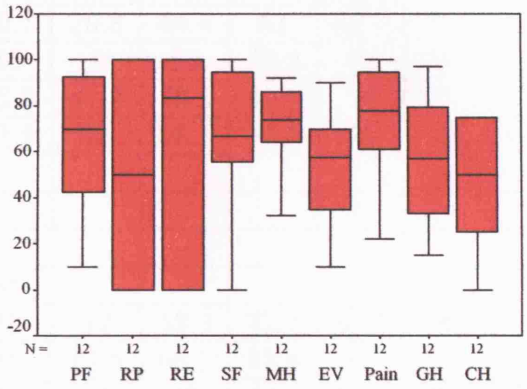
SF-36 scores at 3-months stage



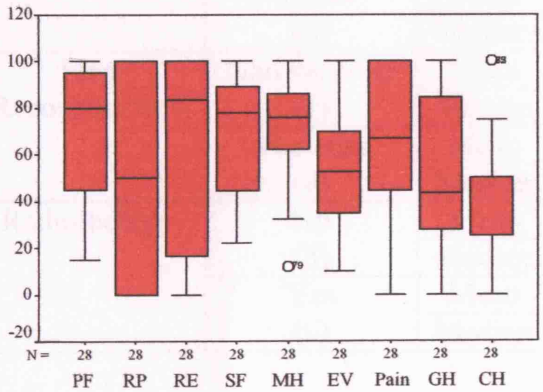
SF-36 scores at 6-months stage



SF-36 scores at 12 months stage



SF-36 scores at 24-months stage



Appendix VII

Table 2.4.2.5-B: SF-36 scores by patients' characteristics in the longitudinal study

			PF	RP	RE	SF	MH	EV	Pain	GH
Patients age	<60 years (5)	Mean	53.2	26.2	33.3	60	60	46	66.7	54.2
		Median	50	.0	33.3	55.6	60	40	77.8	62
	≥60 years (4)	Mean	57.5	50	83.3	94.4	73	55	80.6	57.8
		Median	50	50	83.3	94.4	76	50	77.8	57
Patients gender	Female (3)	Mean	65	41.7	77.8	92.6	76	60	85.2	59.7
		Median	65	25	66.7	88.9	88	55	88.9	62
	Male (6)	Mean	50.1	34.3	44.4	66.7	60.7	45	66.7	53.8
		Median	45	15.5	33.3	77.8	62	40	72.2	57
Marital status	Single (5)	Mean	50.2	20	40	57.8	60.8	44	73.3	43.8
		Median	50	.0	33.3	55.6	60	40	77.8	40
	Married (4)	Mean	61.3	57.8	75	97.2	72	57.5	72.2	70.8
		Median	57.5	53	83.3	100	74	55	77.8	67
Tumour size	T1 & T2 (3)	Mean	65	68.7	77.8		72	55	63	67
		Median	80	75	100		68	60	66.7	72
	T3 & T4 (6)	Mean	50.1	20.8	44.4	63	62.7	47.5	77.8	50.2
		Median	45	.0	50	72.2	56	42.5	77.8	51
Bone resection	No/ Marginal(8)	Mean	55.8	41.4	58.3	81.9	68	52.5	72.2	55
		Median	52.5	28	66.7	94.4	66	50	72.2	57
	Complete (1)	Mean								
		Median								
S.T. resection in relation to teeth	Ant./lat. (1)	Mean								
		Median								
	Post./med. (8)	Mean	52	37	58.3	72.2	63.5	48.1	77.8	53.8
		Median	45	12.5	66.7	88.9	62	42.5	77.8	57
Neck dissection	I-III (6)	Mean	57.5	26	50	75.9	66.7	49.2	70.4	52.2
		Median	57.5	12.5	50	88.9	64	50	72.2	62
	IV-V (3)	Mean	50.3	58.3	66.7	74.1	64	51.7	77.8	63
		Median	35	75	100	100	64	40	77.8	52
Flap Reconstruction	Non vascular (1)	Mean								
		Median								
	Vascular (8)	Mean	53.9	41.4	54.2	73.6	63	49.4	73.6	60.3
		Median	45	28	50	94.4	62	42.5	77.8	62
Radiotherapy	No (3)	Mean	58.3	41.7	77.8	92.6	69.3	53.3	85.2	53
		Median	65	25	66.7	88.9	68	55	88.9	62
	Yes (6)	Mean	53.5	34.3	44.4	66.7	64	48.3	66.7	57.2
		Median	45	15.5	33.3	77.8	62	40	72.2	57

Appendix VIII

Multiple Regression Tables:

Table 2.4.1.11: Multiple regression analysis for anxiety and significantly related variables

		Unstandardized Coefficients		t	P-value	95% Confidence Interval for B	
Model		B	Std. Error			Lower Bound	Upper Bound
1	Constant	18.190	3.257	5.585	.000	11.694	24.687
	Stage	-0.005375	.339	-.158	.875	-.731	.623
	Age	-.105	.036	-2.888	.005	-.177	-.032
	Gender	-2.508	1.168	-2.147	.035	-4.838	-.179

Table 2.4.1.13: Multiple regression analysis for depression and significantly related variables

		Unstandardized Coefficients		t	p-value	95% Confidence Interval for B	
Model		B	Std. Error			Lower Bound	Upper Bound
1	Constant	.919	1.490	.617	.540	-2.058	3.896
	Anxiety	.403	.083	4.872	.000	.238	.568
	N.dissect	1.293	.749	1.725	.089	-.205	2.790
	Stage	-.156	.321	-.486	.628	-.797	.485

Table 2.4.1.21(B): Multiple regressions for the SF-36 domains and preoperative variables

		Unstandardized Coefficients		t	Sig.	95% Confidence Interval for B	
Model		B	Std. Error			Lower Bound	Upper Bound
PF	(Constant)	164.362	32.37	5.08	.000	99.410	229.314
	Patient's age	-1.129	.335	-3.37	.001	-1.800	-.457
	Gender	-11.677	9.136	-1.28	.207	-30.009	6.655
	T. size	-.533	8.170	-.065	.948	-16.927	15.861
	N. node	-15.668	9.419	-1.66	.102	-34.569	3.234
RP	(Constant)	135.212	47.02	2.88	.006	40.717	229.707
	Patient's age	-1.321	.485	-2.72	.009	-2.296	-.346
	Gender	4.046	13.35	.303	.763	-22.788	30.880
	T. size	8.355E-02	11.98	.007	.994	-23.999	24.167
	N. node	-31.530	13.80	-2.28	.027	-59.267	-3.792

Table 2.4.1.23-B: Multiple regression for the EORTC-C30 domains and treatment variables

		Unstandardized Coefficients		t	Sig.	95% Confidence Interval for B	
Model		B	Std. Error			Lower Bound	Upper Bound
SF	(Constant)	111.729	23.366	4.78	.000	64.957	158.501
	Bone resec.	-20.452	10.134	-2.02	.048	-40.738	-.166
	S. tissue resec.	13.044	8.899	1.47	.148	-4.770	30.857
	N. dissection	-19.126	8.239	-2.32	.024	-35.619	-2.633
	Radiotherapy	-7.210	8.179	-.88	.382	-23.582	9.161
FI	(Constant)	-67.316	23.802	-2.83	.006	-114.997	-19.636
	Bone resec.	23.692	10.231	2.32	.024	3.197	44.187
	S. tissue resec.	8.373	9.106	.919	.362	-9.869	26.615
	N. dissection	25.635	8.486	3.02	.004	8.636	42.633
	Radiotherapy	5.349	8.442	.634	.529	-11.561	22.260

Table 2.4.1.27: Multiple regression results for the EORTC H&N35 domains and the significantly related variables

		Unstandardized Coefficients		t	P-value	95% Confidence Interval for B	
Domain		B	Std. Error			Lower Bound	Upper Bound
SO	(Constant)	-45.106	31.603	-1.427	.160	-108.55	18.339
	patient's age	.305	.327	.935	.354	-.351	.961
	Gender	10.527	8.889	1.184	.242	-7.319	28.373
	T. size	19.019	7.984	2.382	.021	2.99	35.048
	N. node	19.252	9.177	2.098	.041	.829	37.675
SC	(Constant)	-1.774	24.015	-.074	.941	-49.99	46.438
	patient's age	-.171	.248	-.691	.493	-.670	.327
	Gender	7.152	6.755	1.059	.295	-6.409	20.713
	T. size	4.675	6.067	.771	.445	-7.505	16.856
	N. node	18.228	6.973	2.614	.012	4.228	32.227
FE	(Constant)	-58.774	35.879	-1.638	.108	-130.8	13.257
	patient's age	.122	.371	.328	.744	-.623	.866
	Gender	16.913	10.092	1.676	.100	-3.348	37.174
	T. size	19.207	9.065	2.119	.039	1.009	37.406
	N. node	14.589	10.419	1.400	.167	-6.327	35.505
SE	(Constant)	-59.034	28.603	-2.064	.044	-116.457	-1.612
	patient's age	.695	.288	2.416	.019	.118	1.273
	Gender	9.822	8.074	1.216	.229	-6.387	26.030
	T. size	3.552	7.108	.500	.619	-10.719	17.822
	N. node	24.648	8.081	3.050	.004	8.426	40.871

Table 2.4.1.27: Multiple regression results for the EORTC H&N35 domains and the significantly related variables (continued)

		Unstandardized Coefficients		t	Sig.	95% Confidence Interval for B	
Model		B	Std. Error			Lower Bound	Upper Bound
Pain	(Constant)	-35.207	19.571	-1.799	.077	-74.382	3.968
	Bone resec.	18.233	8.485	2.149	.036	1.249	35.217
	S. tissue resec.	10.653	7.743	1.376	.174	-4.847	26.153
	N. dissection	9.886	7.165	1.380	.173	-4.457	24.228
	Radiotherpy	7.457	7.127	1.046	.300	-6.809	21.722
SW	(Constant)	-71.374	16.113	-4.430	.000	-103.627	-39.121
	Bone resec.	20.267	6.986	2.901	.005	6.284	34.251
	S. tissue resec.	11.818	6.375	1.854	.069	-.943	24.579
	N. dissection	17.932	5.899	3.040	.004	6.124	29.741
	Radiotherapy	11.805	5.867	2.012	.049	.060	23.550
SP	(Constant)	-52.172	15.239	-3.424	.001	-82.700	-21.645
	Bone resec.	25.804	6.550	3.939	.000	12.681	38.926
	S. tissue resec.	7.837	5.898	1.329	.189	-3.978	19.653
	N. dissection	7.950	5.350	1.486	.143	-2.767	18.667
	Radiotherapy	9.993	5.403	1.849	.070	-.831	20.817
SO	(Constant)	-84.955	19.424	-4.374	.000	-123.851	-46.059
	Bone resec.	31.410	8.369	3.753	.000	14.652	48.169
	S. tissue resec.	11.171	7.456	1.498	.140	-3.759	26.101
	N. dissection	17.374	6.891	2.521	.015	3.574	31.173
	Radiotherapy	19.767	6.883	2.872	.006	5.984	33.550
SC	(Constant)	-35.165	16.902	-2.081	.042	-69.010	-1.320
	Bone resec.	17.650	7.282	2.424	.019	3.068	32.232
	S. tissue resec.	-1.564	6.488	-.241	.810	-14.555	11.427
	N. dissection	13.648	5.997	2.276	.027	1.641	25.656
	Radiotherapy	7.313	5.989	1.221	.227	-4.680	19.306

Table 2.4.1.27: Multiple regression results for the EORTC H&N35 domains and the significantly related variables (continued)

		Unstandardized Coefficients		t	Sig.	95% Confidence Interval for B	
Model		B	Std. Error			Lower Bound	Upper Bound
TE	(Constant)	-37.026	24.408	-1.517	.135	-85.941	11.889
	Bone resec.	18.615	10.843	1.717	.092	-3.116	40.345
	S. tissue resec.	-8.503	9.397	-.905	.369	-27.336	10.330
	N. dissection	14.768	8.730	1.692	.096	-2.726	32.263
	Radiotherapy	18.520	8.449	2.192	.033	1.588	35.452
OM	(Constant)	-57.500	27.184	-2.115	.039	-111.915	-3.085
	Bone resec.	43.908	11.786	3.726	.000	20.317	67.499
	S. tissue resec.	-1.454	10.755	-.135	.893	-22.984	20.075
	N. dissection	15.440	9.952	1.551	.126	-4.482	35.362
	Radiotherapy	11.784	9.899	1.190	.239	-8.030	31.599
DR	(Constant)	-7.130	26.028	-.274	.785	-59.250	44.989
	Bone resec.	2.122	11.313	.188	.852	-20.532	24.776
	S. tissue resec.	-4.527	9.964	-.454	.651	-24.480	15.426
	N. dissection	27.663	9.282	2.980	.004	9.076	46.251
	Radiotherapy	9.364	9.142	1.024	.310	-8.942	27.670
SS	(Constant)	-85.872	26.580	-3.231	.002	-139.139	-32.604
	Bone resec.	21.793	11.451	1.903	.062	-1.155	44.742
	S. tissue resec.	21.172	10.336	2.048	.045	.458	41.885
	N. dissection	15.205	9.443	1.610	.113	-3.718	34.129
	Radiotherapy	21.560	9.451	2.281	.026	2.619	40.501
CO	(Constant)	-32.631	16.826	-1.939	.058	-66.338	1.075
	Bone resec.	11.114	7.240	1.535	.130	-3.390	25.618
	S. tissue resec.	8.534	6.534	1.306	.197	-4.555	21.623
	N. dissection	15.532	6.080	2.554	.013	3.352	27.712
	Radiotherapy	3.816	5.880	.649	.519	-7.964	15.596

Table 2.4.3.1: Regression statistics for predictability of anxiety scores to depression scores

		Unstandardized Coefficients		t	Sig.	95% Confidence Interval for B	
Model		B	Std. Error			Lower Bound	Upper Bound
1	Constant	-3.186E-02	.945	-.034	.973	-1.918	1.854
	Stage	.475	.240	1.977	.052	-.004	.954
	Anxiety	.442	.063	7.006	.000	.316	.568

Dependent Variable: Depression

Table 2.4.3.3: Multiple regression statistics for anxiety predictability to SF-36 domains

		Unstandardized Coefficients		t	P-value	95% Confidence Interval for B	
		B	Std. Error			Lower Bound	Upper Bound
RP	(Constant)	81.890	16.060	5.099	.000	49.824	113.956
	Stage	-2.205	4.033	-.547	.586	-10.257	5.848
	Anxiety	-2.899	1.070	-2.710	.009	-5.036	-.763
RE	(Constant)	86.772	16.352	5.306	.000	54.105	119.440
	stage	.929	4.136	.225	.823	-7.333	9.191
	Anxiety	-3.997	1.090	-3.668	.000	-6.174	-1.820
SF	(Constant)	82.312	10.096	8.153	.000	62.176	102.449
	stage	-.401	2.566	-.156	.876	-5.519	4.717
	Anxiety	-2.193	.674	-3.254	.002	-3.537	-.849
MH	(Constant)	88.447	5.770	15.328	.000	76.932	99.961
	stage	1.799	1.428	1.259	.212	-1.052	4.649
	Anxiety	-3.357	.369	-9.097	.000	-4.094	-2.621
EV	(Constant)	82.080	8.069	10.173	.000	65.975	98.185
	stage	-3.468	2.014	-1.722	.090	-7.488	.551
	Anxiety	-2.285	.518	-4.412	.000	-3.319	-1.251
Pain	(Constant)	84.431	10.083	8.373	.000	64.321	104.542
	stage	-1.141	2.563	-.445	.657	-6.253	3.970
	Anxiety	-1.850	.673	-2.749	.008	-3.192	-.508
GH	(Constant)	84.635	9.819	8.619	.000	65.047	104.223
	stage	-4.938	2.471	-1.998	.050	-9.868	-.008
	Anxiety	-1.897	.642	-2.955	.004	-3.178	-.616

Table 2.4.3.5: Multiple regression statistics for anxiety predictability to EORTC-C30 domains scores

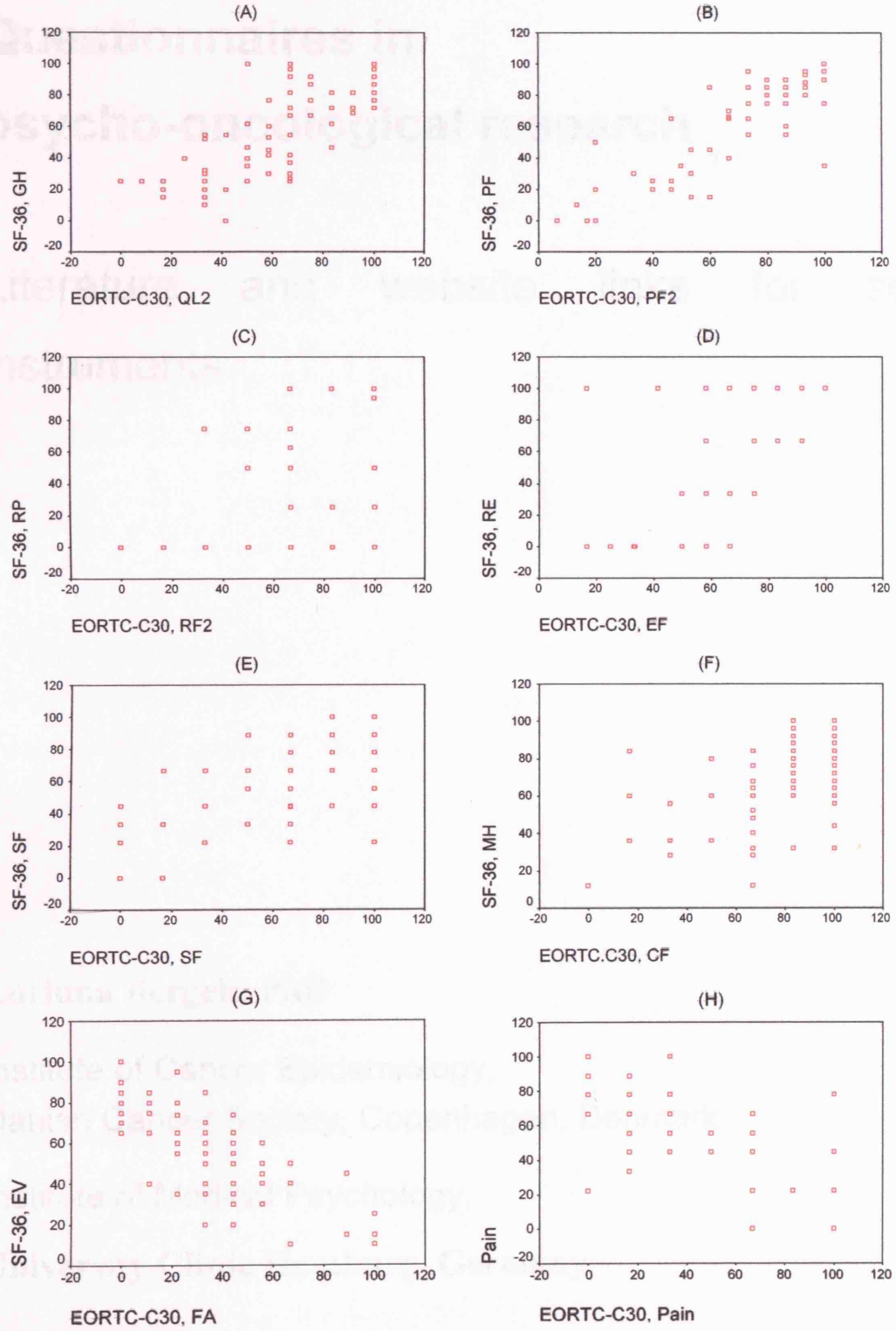
		Unstandardized Coefficients		t	P-value	95% Confidence Interval for B	
		B	Std. Error			Lower Bound	Upper Bound
QL2	(Constant)	79.569	8.545	9.312	.000	62.522	96.616
	stage	.317	2.151	.147	.883	-3.973	4.608
	Anxiety	-2.424	.559	-4.338	.000	-3.538	-1.309
RF2	(Constant)	97.684	11.039	8.849	.000	75.661	119.707
	stage	-3.855	2.761	-1.396	.167	-9.362	1.653
	Anxiety	-2.070	.721	-2.870	.005	-3.509	-.631
EF	(Constant)	96.286	6.118	15.738	.000	84.081	108.491
	stage	-.103	1.530	-.067	.947	-3.155	2.950
	Anxiety	-3.608	.400	-9.024	.000	-4.405	-2.810
CF	(Constant)	92.252	8.899	10.366	.000	74.498	110.005
	stage	.735	2.225	.330	.742	-3.705	5.175
	Anxiety	-2.012	.582	-3.459	.001	-3.172	-.852
SF	(Constant)	101.479	11.678	8.690	.000	78.182	124.776
	stage	-4.003	2.920	-1.371	.175	-9.829	1.823
	Anxiety	-2.386	.763	-3.126	.003	-3.908	-.863
FA	(Constant)	9.332	9.416	.991	.325	-9.452	28.116
	stage	2.781	2.355	1.181	.242	-1.916	7.479
	Anxiety	2.484	.615	4.038	.000	1.257	3.712
NV	(Constant)	-.456	7.599	-.060	.952	-15.616	14.704
	stage	-.288	1.900	-.152	.880	-4.079	3.503
	Anxiety	1.473	.497	2.967	.004	.483	2.464
PA	(Constant)	7.738	11.517	.672	.504	-15.237	30.713
	stage	.194	2.880	.067	.947	-5.552	5.939
	Anxiety	2.744	.753	3.646	.001	1.242	4.245
SL	(Constant)	11.346	14.454	.785	.435	-17.489	40.181
	stage	4.021	3.615	1.112	.270	-3.190	11.232
	Anxiety	2.546	.944	2.695	.009	.661	4.430
AP	(Constant)	19.802	11.793	1.679	.098	-3.724	43.329
	stage	-3.303	2.949	-1.120	.267	-9.187	2.580
	Anxiety	2.473	.771	3.209	.002	.935	4.010
FI	(Constant)	8.193	13.092	.626	.534	-17.938	34.324
	stage	-1.548	3.240	-.478	.634	-8.014	4.919
	Anxiety	2.092	.839	2.493	.015	.417	3.767

Table 2.4.3.7: Multiple regression statistics for anxiety predictability to EORTC H&N35 domains scores

		Unstandardized Coefficients		t	P-value	95% Confidence Interval for B	
		B	Std. Error			Lower Bound	Upper Bound
HNPA	(Constant)	40.711	9.641	4.223	.000	21.477	59.945
	Stage	-7.037	2.459	-2.862	.006	-11.942	-2.131
	Anxiety	1.281	.643	1.992	.050	-.002	2.563
HNSP	(Constant)	-3.403	8.865	-.384	.702	-21.098	14.293
	Stage	2.694	2.213	1.218	.228	-1.722	7.111
	Anxiety	2.004	.569	3.521	.001	.868	3.139
HPSE	(Constant)	18.440	11.907	1.549	.126	-5.327	42.207
	Stage	-1.675	2.943	-.569	.571	-7.548	4.199
	Anxiety	1.820	.758	2.403	.019	.308	3.332
HNSC	(Constant)	-13.495	8.518	-1.584	.118	-30.493	3.503
	Stage	3.060	2.109	1.451	.151	-1.148	7.268
	Anxiety	2.501	.545	4.591	.000	1.414	3.589
HNSX	(Constant)	6.799	14.863	.457	.649	-22.952	36.551
	Stage	.360	3.755	.096	.924	-7.156	7.875
	Anxiety	4.034	.948	4.255	.000	2.136	5.932
HNTE	(Constant)	7.689	12.661	.607	.546	-17.591	32.968
	Stage	-.423	3.174	-.133	.894	-6.761	5.915
	Anxiety	1.982	.812	2.439	.017	.360	3.604
HNOM	(Constant)	1.355	14.320	.095	.925	-27.212	29.923
	Stage	4.289	3.652	1.174	.244	-2.997	11.574
	Anxiety	2.541	.955	2.662	.010	.637	4.446
HNCO	(Constant)	1.280	8.872	.144	.886	-16.428	18.989
	Stage	2.538	2.246	1.130	.262	-1.944	7.021
	Anxiety	1.940	.588	3.301	.002	.767	3.113
HNFI	(Constant)	2.439	12.337	.198	.844	-22.185	27.063
	Stage	-1.702	3.100	-.549	.585	-7.889	4.485
	Anxiety	3.032	.806	3.763	.000	1.424	4.640
HNPK	(Constant)	33.138	19.234	1.723	.089	-5.242	71.518
	Stage	-2.209	4.761	-.464	.644	-11.711	7.292
	Anxiety	3.234	1.230	2.629	.011	.779	5.688
HNWL	(Constant)	23.189	14.957	1.550	.126	-6.665	53.044
	Stage	-6.839	3.701	-1.848	.069	-14.227	.550
	Anxiety	1.924	.959	2.007	.049	.010	3.837

Appendix IX

Plate 2:



Appendix X

Questionnaires in psycho-oncological research

Literature and website links for selected instruments

Corinna Bergelt, PhD

Institute of Cancer Epidemiology,
Danish Cancer Society, Copenhagen, Denmark

Institute of Medical Psychology,

University Clinic Hamburg, Germany

LITERATURE

DISTRESS:

- **Profile of Mood States (POMS)**

Baker F, Denniston M, Zabora J, Polland A, Dudley WN. A POMS short form for cancer patients: psychometric and structural evaluation. Psychooncology. 2002;11:273-81.

- **Impact of Event Scale (IES)**

Horowitz M, Wilner N, Alvarez W. Impact of Event Scale: a measure of subjective stress. Psychosom Med 1979;41:209-18.

- **Distress thermometer**

Roth AJ, Kornblith AB, Batel-Copel L, Peabody E, Scher HI, Holland JC. Rapid screening for psychologic distress in men with prostate carcinoma: a pilot study. Cancer 1998;82:1904-8.

- **Cancer-specific distress questionnaire (CSQ-23R)**

Herschbach P, Keller M, Knight L, Brandl T, Huber B, Henrich G et al. Psychological problems of cancer patients: a cancer distress screening with a cancer-specific questionnaire. Br J Cancer 2004;91:504-11.

HEALTH STATUS:

- **Sickness Impact profile (SIP)**

Gilson BS, Gilson JS, Bergner M, Bobbit RA, Kressel S, Pollard WE et al. The sickness impact profile. Development of an outcome measure of health care. Am J Public Health 1975;65:1304-10.

- **Duke-UNC Health Profile**

Parkerson GR, Jr., Gehlbach SH, Wagner EH, James SA, Clapp NE, Muhlbaier LH. The Duke-UNC Health Profile: an adult health status instrument for primary care. Med Care 1981;19:806-28.

Anxiety AND Depression:

- **Hospital Anxiety and Depression Scale (HADS)**

Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr.Scand 1983;67:361-70.

Razavi D, Delvaux N, Farvacques C, Robaye E. Screening for adjustment disorders and major depressive disorders in cancer in-patients. Br J Psychiatry 1990;156:79-83.
Moorey S, Greer S, Watson M, Gorman C, Rowden L, Tunmore R et al. The factor structure and factor stability of the hospital anxiety and depression scale in patients with cancer. Br J Psychiatry 1991;158:255-9.

- **Memorial anxiety scale for prostate cancer (MAX-PC)**

Roth AJ, Rosenfeld B, Kornblith AB, Gibson C, Scher HI, Curley-Smart T et al. The memorial anxiety scale for prostate cancer: validation of a new scale to measure anxiety in men with with prostate cancer. Cancer 2003;97:2910-8.

- **Center for Epidemiologic Studies Depression Scale (CES-D)**

Radloff, LS. The CES-D scale: A self-report depression scale for research in the general population. Applied Psychological Measurement 1997;1:385-401
Andresen EM, Malmgren JA, Carter WB, Patrick DL. Screening for depression in well older adults: evaluation of a short form of the CES-D (Center for Epidemiologic Studies Depression Scale). Am J Prev Med 1994;10:77-84.

- **Beck Depression Inventory (BDI)**

Beck AT, Ward CH, Mendelson M, Mock J, Erbaugh J. An inventory for measuring depression. Arch Gen Psychiatry 1961;4:561-71.
Beck AT, Steer RA, Garbin MG, Psychometric properties of the Beck Depression Inventory: Twenty-five years of evaluation. Clinical Psychology Review 1988; 8 (1): 77-100.

Quality of Life:

- **Health Survey Short Form (SF-36)**

Ware JE, Jr. SF-36 health survey update. Spine 2000;25:3130-9.

Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473-83.

McHorney CA, Ware JE, Jr., Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. Med Care 1993;31:247-63.

McHorney CA, Ware JE, Jr., Lu JF, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36): III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. Med Care 1994;32:40-66.

- **World Health Organisation Quality of Life Questionnaire (WHOQOL-BREF)**

Skevington SM, Lotfy M, O'Connell KA. The World Health Organization's WHOQOL-BREF quality of life assessment: psychometric properties and results of the international field trial. A report from the WHOQOL group. Qual.Life Res 2004;13:299-310.

- **The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)**

Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ et al. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. J Natl Cancer Inst 1993;85:365-76.

- **Functional Assessment of Cancer Therapy Scale General (FACT-G)**

Cella DF, Tulsky DS, Gray G, Sarafian B, Linn E, Bonomi A et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. J Clin Oncol 1993;11:570-9.

- **Functional Assessment of Chronic Illness Therapy (FACIT)**

Webster K, Cella D, Yost K. The Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System: properties, applications, and interpretation. Health Qual.Life Outcomes. 2003;1:79.

Coping:

- **Mental Adjustment to Cancer (MAC)**

Watson M, Greer S, Young J, Inayat Q, Burgess C, Robertson B. Development of a questionnaire measure of adjustment to cancer: the MAC scale. Psychol Med 1988;18:203-9.

Greer S, Moorey S, Watson M. Patients' adjustment to cancer: the Mental Adjustment to Cancer (MAC) scale vs clinical ratings. J Psychosom Res 1989;33:373-7.
Nordin K, Berglund G, Terje I, Glimelius B. The Mental Adjustment to Cancer Scale--a psychometric analysis and the concept of coping. Psychooncology. 1999;8:250-9.

- **System of Beliefs Inventory (SBI-15R)**

Holland JC, Kash KM, Passik S, Gronert MK, Sison A, Lederberg M et al. A brief spiritual beliefs inventory for use in quality of life research in life-threatening illness. Psychooncology. 1998;7:460-9.

Social Support:

- **Social Support Questionnaire Transactions / Social Support Questionnaire Satisfaction (SSQT / SSQS)**

Doeglas D, Suurmeijer T, Briancon S, Moum T, Krol B, Bjelle A et al. An international study on measuring social support: interactions and satisfaction. Soc.Sci Med 1996;43:1389-97.

- **International Classification of Functioning, Disability and Health (ICF):**

Stucki G, Ewert T, Cieza A. Value and application of the ICF in rehabilitation medicine. Disabil.Rehabil 2003;25:628-34.
Stucki G, Ewert T, Cieza A. Value and application of the ICF in rehabilitation medicine. Disabil.Rehabil 2002;24:932-8.
Kearney PM, Pryor J. The International Classification of Functioning, Disability and Health (ICF) and nursing. J Adv.Nurs 2004;46:162-70.

WEBSITES:

Information on instruments – databases:

- **QOLID the Quality Of Life Instruments Database:** http://www.qolid.org

  QOLID currently contains: Description of 454 instruments
  304 review copies of original instruments
  Review copies of 241 translations
  Review copies of 112 user manuals
  Description of 80 databases

- **Patient-assessed health instruments**: http://phi.uhce.ox.ac.uk

  The Patient-assessed Health Instruments (PHI) website is designed to inform the selection of patient-assessed health instruments through the provision of a bibliographic database, selection criteria, published reports and relevant links.
  The bibliography contains over 7000 records that relate to the development and testing of instruments

- **Australian Center on Quality of life**:
  http://acqol.deakin.edu.au/instruments/instrument.php

Specific instruments:

- **SF-36:** http://www.sf-36.org
- **FACT-G, FACIT:** http://www.facit.org/
- **EORTC QLQ-C30 and modules:** http://www.eortc.be/home/qol/ExplQLQ-C30.htm
- **WHOQOL and WHOQOL-BREF:** http://www.who.int/evidence/assessment-instruments/qol/

International Classification of Functioning, Disability and Health:

www3.who.int/icf

Appendix XI

THE U.K. SF-36: AN ANALYSIS AND INTERPRETATION MANUAL

A guide to health status measurement with particular reference to the Short Form 36 Health Survey

CRISPIN JENKINSON
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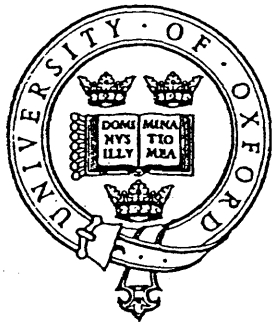

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SF-36 SCORING SYSTEM

The instructions given below are for scoring the eight dimensions of the U.K. SF-36 reproduced in this manual. They show;

- which items compose each dimension;
- the coding system for each item. *Important note: not all items in a domain are coded in the same manner.* For example, in the mental health dimension items 9d and 9h are coded in the reverse manner to 9b, 9c and 9f;
- the scoring algorithms for each dimension.

If you are interested in creating the summary scale scores (the Physical Component Summary (PCS) and the Mental Component Summary (MCS)) from UK SF-36 data then please see page 39.

1. Coding items:

Physical function

3a, 3b, 3c, 3d, 3e, 3f, 3g, 3h, 3i, 3j	Yes, limited a lot = 1 Yes, limited a little = 2 No, not limited at all = 3

Role limitation due to physical problems

4a, 4b, 4c, 4d	Yes = 0 No = 1

Role limitation due to emotional problems

5a, 5b, 5c	Yes = 0 No = 1

Social functioning

6	Not at all = 5 Slightly = 4 Moderately = 3 Quite a bit = 2 Extremely = 1
9j	All of the time = 1 Most of the time = 2 A good bit of the time = 3 Some of the time = 4 A little of the time = 5 None of the time = 6

Mental health

9b, 9c, 9f	All of the time = 1 Most of the time = 2 A good bit of the time = 3 Some of the time = 4 A little of the time = 5 None of the time = 6
9d, 9h	All of the time = 6 Most of the time = 5 A good bit of the time = 4 Some of the time = 3 A little of the time = 2 None of the time = 1

Energy/vitality

9a, 9e	All of the time = 6 Most of the time = 5 A good bit of the time = 4 Some of the time = 3 A little of the time = 2 None of the time = 1
9g, 9i	All of the time = 1 Most of the time = 2 A good bit of the time = 3 Some of the time = 4 A little of the time = 5 None of the time = 6

Pain

7

None = 6
Very mild = 5
Mild = 4
Moderate = 3
Severe = 2
Very severe = 1

8

Not at all = 5
A little bit = 4
Moderately = 3
Quite a bit = 2
Extremely = 1

General health Perception

1

Excellent = 5
Very good = 4.4
Good = 3.4
Fair = 2
Poor = 1

10a, 10c

Definitely true = 1
Mostly true = 2
Not sure = 3
Mostly false = 4
Definitely false = 5

10b, 10d

Definitely true = 5
Mostly true = 4
Not sure = 3
Mostly false = 2
Definitely false = 1

Change in health

2

Much better now = 5
Somewhat better = 4
About the same = 3
Somewhat worse = 2
Much worse = 1

2. Calculating dimension scores

Physical function (PF)

PF = 3a + 3b + 3c + 3d + 3e + 3f + 3g + 3h + 3i + 3j
Physical function score = ((PF-10)/20) * 100

Role limitation due to physical problems (RP)

RP = 4a + 4b + 4c + 4d
Role limitation due to physical problems score = (RP/4)*100

Role limitation due to emotional problems (RE)

RE = 5a + 5b + 5c
Role limitations due to emotional problems score = (RE/3)*100

Social functioning (SF)

SC = 6 + 9j
Social functioning score = ((SC-2)/9)*100

Mental health (MH)

MH = 9b + 9c + 9d + 9f + 9h
Mental health score = ((MH-5)/25)*100

Energy/vitality (EV)

EV = 9a + 9e + 9g + 9i
Energy/vitality score = ((EV-4)/20)*100

Pain (P)

P = 7 + 8
Pain = ((p-2)/9)*100

General health Perception (GHP)

HP = 1 + 10a + 10b + 10c + 10d
General health perceptions = ((GHP-5)/20)*100

Change in health (CH)

CH = 2
Change in health score = ((CH - 1)/4)*100

Notes:

This scoring system is for use with the UK SF-36, as reproduced in this manual.

Do not present CH data in terms of means and standard deviations.

Where items are missing from multi-item scales the developers suggest an estimate may be calculated. They suggest that in those instances where over half of the items are completed missing values can be imputed as the average of completed items. We have not employed this strategy in the data presented in this report. We strongly advise that users do not impute data in small data sets.

Ownership of this report does not constitute or imply a right to use this questionnaire. Potential users must inform the Medical Outcomes Trust (see page 43).

Appendix XII

EORTC QLQ-C30 Scoring Manual

The EORTC QLQ-C30

Introduction

The EORTC quality of life questionnaire (QLQ) is an integrated system for assessing the health-related quality of life (QoL) of cancer patients participating in international clinical trials. The core questionnaire, the QLQ-C30, is the product of more than a decade of collaborative research. Following its general release in 1993, the QLQ-C30 has been used in a wide range of cancer clinical trials, by a large number of research groups; it has additionally been used in various other, non-trial studies.

This manual contains scoring procedures for the QLQ-C30 versions 1.0, (+3), 2.0 and 3.0; it also contains summary information about supplementary modules.

All publications relating to the QLQ should use the scoring procedures described in this manual.

This manual will be updated at regular intervals, to reflect future changes to the QLQ and to incorporate new supplementary modules.

Background

EORTC

The European Organization for Research and Treatment of Cancer (EORTC) was founded in 1962, as an international non-profit organization. The aims of the EORTC are to conduct, develop, co-ordinate and stimulate cancer research in Europe by multidisciplinary groups of oncologists and basic scientists. Research is accomplished mainly through the execution of large, prospective, randomized, multicentre, cancer clinical trials.

The EORTC Central Office Data Center, created in 1974, is concerned with all aspects of phase II and phase III cancer clinical trials, from their design to the publication of the final results. Since its inception, over 80,000 patients have been entered in trials handled by the EORTC Data Center.

In 1980, the EORTC created the Quality of Life Study Group, which in 1986 initiated a research programme to develop an integrated, modular approach for evaluating the QoL of patients participating in cancer clinical trials.

EORTC QLQ-C36

A first generation core questionnaire, the EORTC QLQ-C36, was developed in 1987. This 36-item questionnaire was designed to be (1) cancer specific, (2) multidimensional in structure, (3) appropriate for self-administration (i.e. brief and easy to complete), and (4) applicable across a range of cultural settings. Detailed results of the international field testing of the EORTC QLQ-C36 have been reported (Aaronson *et al.*, 1991). While the overall psychometric results were promising, they also pointed to some areas in which the questionnaire could benefit from further development. Most of the revision involved only minor changes in the wording of items. A few items were found to be non-informative, and were discarded. The only scale requiring substantial revision, because of inadequate reliability, was the eight-item emotional functioning scale. In the next generation of the instrument, this scale was substituted by a four-item emotional functioning scale that had been used previously in EORTC clinical trials.

EORTC QLQ-C30 version 1.0

A second-generation core questionnaire, the first version of the 30-item EORTC QLQ-C30 (Appendix 1a), was subsequently developed. The content areas covered by the questionnaire reflect the multi-dimensionality of the QoL construct. This questionnaire was field tested in a cross-cultural sample of lung cancer patients in 13 countries to confirm the hypothesised scale structure, to establish reliability and to evaluate validity (Aaronson *et al.*, 1993).

The QLQ-C30 version 1.0 (QLQ-C30(v1)) incorporates five functional scales (physical, role, cognitive, emotional, and social), three symptom scales (fatigue, pain, and nausea and vomiting), a global health status / QoL scale, and a number of single items assessing additional symptoms commonly reported by cancer patients (dyspnoea, loss of appetite, insomnia, constipation and diarrhoea) and perceived financial impact of the disease.

EORTC QLQ-C30 (+3)

The third generation core questionnaire, the 33-item EORTC QLQ-C30(+3) (Appendix 1b), arose following international testing of the QLQ-C30(v1), when refinement of the questionnaire by adding three new test items was recommended. Two of these test items (QLQ-C30(+3)/Q_{26}, and QLQ-C30(+3)/Q_{27}) were introduced as possible alternatives to the two-item role functioning scale (QLQ-C30(v1)/Q_6, QLQ-C30(v1)/Q_7), which was found to have sub-optimal internal consistency in previous studies. The third new test item, overall health (QLQ-C30(+3)/Q_{32}), was evaluated as a possible replacement for the overall physical condition item (QLQ-C30(v1)/Q_{29}) in the global health status / QoL scale, and employed the same 7-point response scale as the other two questions in that scale.

EORTC QLQ-C30 version 2.0

The QLQ-C30(+3) was an interim version, which retained all the original questions of the QLQ-C30 version 1.0 while evaluating the additional three items. There was a marked improvement in the internal consistency of the new role functioning scale. The new overall health item places less emphasis upon physical functioning, and did not alter the internal consistency. Having formally validated these new items, the older questions were replaced by the new ones (Osoba *et al.*, 1997). The result was the 30-item version 2.0 of the QLQ, the QLQ-C30(v2) (Appendix 1c).

EORTC QLQ-C30 version 3.0

Version 3.0 of the QLQ-C30 differs from version 2.0 in that it has four-point scales for the first five items (QLQ-C30(v3), Appendix 1d). These are coded with the same response categories as item 6 to 28, namely "Not at all", "A little", "Quite a bit" and "Very much." To allow for these categories, question 4 has been re-worded as "Do you have to stay in a bed or a chair during the day?"

Version 3.0 is currently the standard version of the QLQ-C30, and should be used for all new studies unless investigators wish to maintain compatibility with previous studies, which used an earlier version of the QLQ-C30.

Citation and Availability

Citation in published reports
Any publications which describe the use of the EORTC QLQ-C30 or its modules, or which describe analyses of data arising from application of these questionnaires, should explicitly cite the following reference:

> Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, Filiberti A, Flechtner H, Fleishman SB, de Haes JCJM, Kaasa S, Klee MC, Osoba D, Razavi D, Rofe PB, Schraub S, Sneeuw KCA, Sullivan M, Takeda F.
> The European Organization for Research and Treatment of Cancer QLQ-C30: A quality-of-life instrument for use in international clinical trials in oncology.
> *Journal of the National Cancer Institute* 1993; 85: 365-376.

For details of the scoring procedure, a suggested format of citation for this manual is:

> Fayers PM, Aaronson NK, Bjordal K, Curran D, Groenvold M on behalf of the EORTC Quality of Life Study Group.
> *The EORTC QLQ-C30 Scoring Manual (2nd Edition).*
> Published by: European Organization for Research and Treatment of Cancer, Brussels 1999.

Contact address
For information about terms and conditions for using the questionnaire, please contact the Quality of Life Unit, EORTC Data Center.

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Scoring procedures

General principles of scoring

The QLQ-C30 is composed of both multi-item scales and single item measures. These include five functional scales, three symptom scales, a global health status / QoL scale, and six single items. Each of the multi-item scales includes a different set of items - no item occurs in more than one scale.

All of the scales and single-item measures range in score from 0 to 100. A high scale score represents a higher response level.
Thus a **high score for a functional scale** represents a *high / healthy level of functioning*,
a **high score for the global health status / QoL** represents a *high QoL*,
but a **high score for a symptom scale / item** represents a *high level of symptomatology / problems*.

The principle for scoring these scales is the same in all cases:

1. Estimate the average of the items that contribute to the scale; this is the *raw score*.

2. Use a linear transformation to standardise the raw score, so that scores range from 0 to 100; a higher score represents a higher ("better") level of functioning, or a higher ("worse") level of symptoms.

Coding of the scoring procedure is presented in Appendix 3 for several major statistical packages.

Technical Summary

In practical terms, if items $I_1, I_2, \ldots I_n$ are included in a scale, the procedure is as follows:

- **Raw score**
  Calculate the raw score
  $RS = (I_1 + I_2 + \ldots + I_n)/n$

- **Linear transformation**
  Apply the linear transformation to 0-100 to obtain the score S.
  Functional scales: $S = \left\{1 - \frac{(RS-1)}{range}\right\} \times 100$
  Symptom scales / items: $S = \{(RS-1)/range\} \times 100$
  Global health status / QoL: $S = \{(RS-1)/range\} \times 100$
  Range is the difference between the maximum possible value of RS and the minimum possible value. The QLQ-C30 has been designed so that all items in any scale take the same range of values. Therefore, the range of RS equals the range of the item values. Most items are scored 1 to 4, giving *range* = 3. The exceptions are the items contributing to the global health status / QoL, which are 7-point questions with *range* = 6, and the initial yes/no items on the earlier versions of the QLQ-C30 which have *range* = 1.

Scoring the EORTC QLQ-C30 version 3.0

Table 1: Scoring the QLQ-C30 version 3.0

	Scale	Number of items	Item range*	**Version 3.0** Item numbers	Function scales
Global health status / QoL					
Global health status/QoL (revised)†	QL2	2	6	29, 30	
Functional scales					
Physical functioning (revised)†	PF2	5	3	1 to 5	F
Role functioning (revised)†	RF2	2	3	6, 7	F
Emotional functioning	EF	4	3	21 to 24	F
Cognitive functioning	CF	2	3	20, 25	F
Social functioning	SF	2	3	26, 27	F
Symptom scales / items					
Fatigue	FA	3	3	10, 12, 18	
Nausea and vomiting	NV	2	3	14, 15	
Pain	PA	2	3	9, 19	
Dyspnoea	DY	1	3	8	
Insomnia	SL	1	3	11	
Appetite loss	AP	1	3	13	
Constipation	CO	1	3	16	
Diarrhoea	DI	1	3	17	
Financial difficulties	FI	1	3	28	

* *Item range* is the difference between the possible maximum and the minimum response to individual items; most items take values from 1 to 4, giving *range* = 3.

† (revised) scales are those that have been changed since version 1.0, and their short names are indicated in this manual by a suffix "2" – for example, PF2.

For all scales, the *RawScore*, *RS*, is the mean of the component items:

$$RS = RawScore = (I_1 + I_2 + ... + I_n)/n$$

Then for **Functional scales**:

$$Score = \left\{1 - \frac{(RS - 1)}{range}\right\} \times 100$$

and for **Symptom scales / items** and **Global health status / QoL:**

$$Score = \{(RS - 1)/range\} \times 100$$

Examples:

Emotional Functioning

$$RawScore = (Q_{21} + Q_{22} + Q_{23} + Q_{24})/4$$

$$\text{EF } Score = \{1 - (RawScore - 1)/3\} \times 100$$

Fatigue

$$RawScore = (Q_{10} + Q_{12} + Q_{18})/3$$

$$\text{FA } Score = \{(RawScore - 1)/3\} \times 100$$

Head & Neck cancer module: QLQ-H&N35

The head & neck cancer module is meant for use among a wide range of patients with head & neck cancer, varying in disease stage and treatment modality (i.e. surgery, radiotherapy and chemotherapy) (Bjordal & Kaasa, 1992; Bjordal *et al.*, 1994; Bjordal *et al.*, 1998). The module comprises 35 questions assessing symptoms and side effects of treatment, social function and body image/sexuality (Appendix 2b). The module has been developed according to the guidelines, and pretested on patients from Norway, Sweden, Denmark, the UK and French-speaking Belgium. It has been field tested in Norway, Sweden and The Netherlands, and in a large cross-cultural study involving more than ten countries (EORTC Protocol 15941).

Scoring of the head & neck cancer module:
The head & neck cancer module incorporates seven multiple-item scales that assess pain, swallowing, senses (taste and smell), speech, social eating, social contact and sexuality. There are also eleven single items. For all items and scales, high scores indicate more problems (i.e. there are no function scales in which high scores would mean better functioning).

The scoring approach for the QLQ-H&N35 is identical in principle to that for the symptom scales / single items of the QLQ-C30.

Scale name	Scale	Number of items	Item range*	QLQ-H&N35 Item numbers
Symptom scales / items				
Pain	HNPA	4	3	1,2,3,4
Swallowing	HNSW	4	3	5,6,7,8
Senses problems	HNSE	2	3	13,14
Speech problems	HNSP	3	3	16,23,24
Trouble with social eating	HNSO	4	3	19,20,21,22.
Trouble with social contact	HNSC	5	3	18,25,26,27,28
Less sexuality	HNSX	2	3	29,30
Teeth	HNTE	1	3	9
Opening mouth	HNOM	1	3	10
Dry mouth	HNDR	1	3	11
Sticky saliva	HNSS	1	3	12
Coughing	HNCO	1	3	15
Felt ill	HNFI	1	3	17
Pain killers	HNPK	1	1	31
Nutritional supplements	HNNU	1	1	32
Feeding tube	HNFE	1	1	33
Weight loss	HNWL	1	1	34
Weight gain	HNWG	1	1	35

* "Item range" is the difference between the possible maximum and the minimum response to individual items.

Missing data

Missing data may be classified as either missing items (one or more missing items within a questionnaire), or missing forms (the whole questionnaire is missing for a patient).

Missing items

Sometimes a patient will fail to answer a few questions on the QLQ-C30. Our experience to date suggests that less than 2% of patient data will be missing for the QLQ core questionnaire. However, supplementary modules addressing, for example, sexuality issues may have more serious problems with patient compliance. In theory it is important to distinguish between items which are accidentally missing (commonly described as "missing completely at random"), and items which are missing for a particular reason. For example, if patients feel very poorly with respect to one item they might wish to avoid answering that question. In practice, however, there is likely to be no way of deciding whether there was a specific reason for the missing values and, in general, it would seem likely that most missing items occur completely at random. In such cases the investigator may wish to calculate the scores based upon those items that were completed, possibly by "imputing" or estimating the missing item.

Various statistical methods exist for imputing values. One might, for example, use multivariate techniques that attempt to estimate the most likely value given information about (a) that patient's previous responses to the same item, (b) other patients' responses at a similar stage in their disease progression and therapy, or (c) the inter-relations and covariance structure with other items. Fayers *et al.* (1998a) and Curran *et al.* (1998b) describe methods of analysis.

A simple method for imputing items from multi-item scales, which has been used by many QoL instruments, is the following: if at least half of the items from the scale have been answered, assume that the missing items have values equal to the average of those items which *are* present for that respondent (Ware *et al.*, 1993; Morris & Coyle, 1994). However, Fayers *et al.*, 1998a discuss the conditions under which this rule is appropriate, and suggest that caution should be exercised. Application of this method of imputation is simpler than it perhaps seems; it can be shown that this is algebraically equivalent to using all items which were completed, and applying the equations already given under "Scoring procedures" for calculating the scale scores; the missing items are simply ignored when making the calculations. Hence the above equations for multi-item scales can be used whenever at least half the items are completed.

For example, role functioning (RF) and cognitive functioning (CF) each contain 2 items, and so these scales can be estimated whenever one of their constituent items is present; physical functioning contains 5 items, and so at least 3 need to have been completed. Using this method, none of the single-item measures can be imputed.

Example:
Emotional Functioning if Q23 is missing (3 items not missing)

$$RawScore = (Q_{21} + Q_{22} + Q_{24})/3$$

$$\text{EF } Score = \{1 - (RawScore - 1)/3\} \times 100$$

Summary – Missing items

- Have at least half of the items from the scale been answered?
- If *Yes*, use all the items that were completed, and apply the standard equations given on the previous pages for calculating the scale scores; ignore any items with missing values when making the calculations.
- If *No*, set scale score to missing.
- For single-item measures, set score to missing.

Missing forms

As experience with QoL research has increased among the cancer treatment community, so has the need for innovative strategies to prevent, identify and deal with the problem of missing data. In addition to the potential for incomplete data that can occur when introducing researchers to a relatively new type of patient outcome, QoL assessments are likely to be missed because of negative events that are experienced by patients, such as treatment toxicities, and patients dropping out due to disease progression or even death. Successful integration of QoL endpoints into clinical trials, therefore, involves a comprehensive approach encompassing issues of research design, study implementation, and statistical analysis methods.

When initiating a clinical trial it is essential that an adequate infrastructure be in place to ensure the study is managed properly and efficiently. The EORTC study group has developed a manual *Guidelines for Assessing Quality of Life in EORTC Clinical Trials* which details the issues which need to be addressed in the design of a clinical trial to ensure that QoL is adequately addressed in the study (Young, 1999). Education and training of clinical staff regarding the importance of QoL endpoints, combined with centralised quality assurance strategies, are crucial to the successful integration of these endpoints into clinical trials. Even with such efforts, however, there will be incomplete observations. Although the problem of missing forms is not unique to QoL research, it presents an unusual challenge in that the information is provided by patient self-report at a particular point in time, and thus cannot be retrieved at a later date from medical charts, as is often possible with other types of clinical data.

It is useful to document and report the extent of missing data and the reasons for missing data. By identifying the reasons for missing questionnaires it may be possible to learn more about the problems of collecting QoL questionnaires, e.g. institution-related factors, and circumvent these problems in future research. The reasons why questionnaires have not been completed may also provide useful information to take into account at the time of analysis. For example, if the main reasons for observing missing questionnaires is administrative failure, then provided the extent of missingness is not too large, the missing forms may not pose too much of a problem. However, if the main reasons for missingness are due to patients feeling too ill to fill out the questionnaire, care has to be taken as there may be a bias in terms of reporting of results. Curran *et al.* (1998b) discussed the issue of bias and suggested how it may be possible to reduce the bias by taking covariates into account. Curran *et al.* (1998a) also showed how logistic regression models could be used to evaluate statistically the association between compliance and selected factors.

Troxel *et al.* (1998) described some statistical techniques for assessing and analysing QoL data in the presence of incomplete observations.

Various imputation approaches have been suggested for imputing values, e.g. mean imputation, regression imputation and last observation carried forward. A major advantage of imputation is that, once the values have been filled in, standard complete data methods of analysis can be used. Some problems do exist using single imputation, e.g. an imputed value is treated as if it was an observed value. This can cause problems, as summary statistics such as percentiles, variances and confidence intervals may have incorrect estimates and hence any inferences that are drawn may be misleading. Detailed descriptions of imputation techniques may be found in Little and Rubin, (1987) and Rubin (1987).

Summary – Missing Forms

Sufficient care and attention should be taken at the design stage of a study to ensure an adequate infrastructure, including appropriate personnel and material, is available to carry out the study. No matter how well the analysis is thought out and how accurate assumptions are about the missing data process, inferences based on incomplete data are not as convincing as inferences based on a complete dataset.

Theory of scaling

The scaling technique described above is based upon the widely applied Likert method of summated scales (Likert, 1952; Nunnally, 1994), in which the constituent items within each scale are simply summed. This makes several assumptions about the nature of the items, the most important of which are (a) that it is appropriate to give equal weight to each item, and (b) that each item is graded on a linear or equal-interval scale. Both these assumptions are questionable, and it might be thought that more sophisticated scaling and scoring procedures would be preferable. Fortunately, however, it has been shown that simple linear scoring systems are surprisingly robust (Dawes, 1979). This has led Cox *et al.* (1992) to propose that "simple integer scoring is likely to be enough for many purposes."

Linearity of items

Methods for assessing the adequacy of linear scores have been reviewed by Cox & Wermuth (1994). At present we have no grounds to believe that the EORTC QLQ items are sufficiently non-linear to warrant any correction before using them in summated scales.

Weighting of items

The use of weights is a far more complex question. Alternative methods for assigning weights include:

- Analysis techniques such as factor analysis or other data-orientated weights (e.g. Gorsuch, 1983; Olschewski & Schumacher, 1990). However, many authors have noted the inherent instability of factor scores, and recommend that the use of factor analysis should be confined to exploring factor structures and testing hypotheses.
- Techniques which attempt to elicit patients' personal utilities or preferences. Drummond *et al.* (1987) describes some of the principal methods that are based upon either the "standard gamble" or the "time trade-off" method. Cox *et al.* (1992) offer a critique of the use of utility methods, and in particular time trade-off, in the context of clinical trials.
- Assignment of arbitrary weights according to opinions of the patients, the investigators, or similar groups (e.g. Simes, 1986).

The papers by Cox *et al.* (1992) and Olschewski & Schumacher (1990), and the book by Streiner & Norman (1995) contain useful discussions of alternative scaling systems and the problems of choosing, applying and evaluating scaling methods. The inherent difficulties, together with the relative robustness of simple methods, have led many QoL instruments to employ the Likert summated score method (Ware *et al.*, 1993).

The EORTC Quality of Life Study Group is currently exploring alternative scoring procedures, including the use of Rasch models and item response theory (IRT). Structural equation modelling is also being used to investigate higher order factors. At the present time we recommend using scales based upon unweighted summed scores. Also, it should be noted that we caution strongly against the use of a total, global score based upon the sum of all items. The Global health status / QoL scale (based upon Q_{29} and Q_{30} in the QLQ-C30(v3)) should be used as the overall summary measure.

Summary

We currently advocate (unweighted) summated scales. However, work is in progress to explore alternative techniques for evaluating QLQ-C30 scores.

Interpretation of scores

As described in this manual, the raw QLQ-C30 scores can be transformed to scores ranging from 0 to 100. The use of these transformed scores has several advantages, but transformed scores may be difficult to interpret. For example, what does an Emotional Function score of 60 or a difference of 15 mean? Also, there are no grounds for regarding, say, an Emotional Function score of 60 as being equally good or bad as scores of 60 on the other functioning scales. However, there are a number of ways to ease the interpretation of QLQ-C30 results.

- One can *report the raw scores* in addition to the transformed scores. For example, it may be clinically relevant to know the proportion of patients that are 'Quite a bit' or 'Very much' constipated. This also applies to results from multi-item scales when the responses to the individual items are of interest. In some cases it may be useful to dichotomise scores, for example by grouping scores into 'Not at all' vs. 'Any extent'.

- The scores can be *compared against published data*, e.g. by using the data for comparable groups of patients published in the *EORTC QLQ-C30 Reference Values* manual (Fayers *et al.*, 1998b). In the *Reference Values* manual, data are shown for the main cancer sites, divided by stage of disease. General population data based on large random samples from the general population in Norway and Denmark are also published (Hjermstad *et al.*, 1998, Klee *et al.*, 1997).

Changes in scores over time and *differences between groups* may be more difficult to interpret than absolute scores. The fact that a change is statistically significant does not necessarily imply that it also has clinical significance. Lydick and Epstein reviewed the different approaches used to define the 'Minimal Clinically Important Difference' and grouped these into *anchor-based* and *distribution-based interpretations* (Lydick & Epstein, 1993).

Anchor-based interpretations compare the changes seen in QoL scores ('anchored') against other clinical changes or results. Examples of such approaches used with the QLQ-C30 include:

- Osoba *et al.* developed the *Subjective Significance Questionnaire* (SSQ) (Osoba *et al.*, 1998). The SSQ asks patients about *perceived changes* in physical, emotional, and social functioning and in global QL, using a 7-point scale ranging from 'much worse' over 'no change' to 'much better'. Patients filled in the QLQ-C30 at two occasions. At the second completion they also filled in the SSQ. Patients who reported 'a little' change for better or worse on a particular scale (function or symptom) had QLQ-C30 changes about 5 to 10. Those reporting 'moderate' change had changed about 10 to 20, and 'very much' change corresponded to a change greater than 20.

- King used data from 14 published studies employing the QLQ-C30 or the QLQ-C36, grouping patients according to performance status, weight loss, toxicity, and extent or severity of disease (King, 1996). For each QLQ-C30 scale, the article shows differences in mean scores found between groups differing with respect to the clinical criteria.

Distribution-based interpretations are based on the statistical distributions of results. The most commonly used statistics are Cohen's *effect size* (ES), which relates the observed change to the baseline standard deviation (Cohen, 1988), or the *standardised response mean* (SRM), which uses the standard deviation of the change. In both Osoba's and King's articles, effect sizes were found to increase in concordance with increasing changes in QLQ-C30 scores and SSQ ratings.

Appendix XIII

Quality of life in Head and Neck Cancer patients

Patient's name: ..... **Hospital No**.....

DOB: ...../...../..... **Gender** M / F **Marital Status** .....

Address: .... **Post code** .....

Type of education:
1- Primary school 2- secondary vocational school

3- Intermediate vocational/ high school 4- Higher vocational school or university

Employment status: 1- Employed 2- Not employed

Family income level: 1- Below modal 2- Modal 3- Above modal

Alcohol abuse: 1- Yes 2- No

Smoking: 1- Yes 2- No

Diagnosis: ..... **Date:** ...../...../.....

Tumour site 1- Lip Cheek 2- Hard palate 3- Floor of mouth 4- Anterior 2/3 tongue
5- Soft palate 6- Retromolar pad 7- Alveolar 8- Tongue base 9- Other

Clinical stage (TNM) ..... **Recurrence** Yes No

Stage of Treatment: 1) Preoperative 2) $\leq$ 3 months 3) $\leq$ 1 year 4) > 1 year

Surgery: A- Bone: 1- no or rim resection 2- Segment resection

B- Soft tissue: 1- Anterior / Lateral 2- Posterior / Medial

C- Neck dissection: 1- I-III 2- IV-V

D- Reconstruction: 0- Non vascular flap 2- Vascular flap

Radiotherapy: .....

Chemotherapy: .....

Patients and care givers needs questionnaire

	Scale	Strongly agree	Fairly agree	Fairly disagree	Strongly disagree	Comments
1	Confidence in the health professionals I meet					
2	Receive honest, clear and efficient information					
3	Given information sensitively					
4	Chance to join in choice of treatment					
5	Information about complications and treatment burden					
6	Adequate time to discuss issues with doctors					

7	Have information sources other than doctors					
8	Know about hospital services					
9	Help and support from care specialist (such as nurses and physiotherapist)					
10	Help and advice on diet and food					
11	Treated with respect at all times					
12	Opportunities for meeting others in a similar situation					
13	Support in dealing with changes in the way I look					

14	Maintaining a sense of control in my life					
15	Help in dealing with distressing feelings					
16	Support with getting out and about socially					
17	Support in dealing with housework					
18	Support from family and relatives					
19	Support from friends and neighbours					
20	Support and advice in dealing with financial matters					

21	Having time for myself					
22	Support from a spiritual advisor					
23	Having high hopes for the future					
Suggestions:						

Thank you

Appendix XIV

Table 3.4.7: Patients SF-36 domains scores at different times

Time	SF-36 domains	median	mean
Preoperative	Physical functioning	85	85
	Role limitation due to physical problems	0	0
	Role limitation due to emotional problems	33	33
	Social functioning	67	67
	Mental health	60	60
	Energy and vitality	45	45
	Pain	33	33
	General health perception	35	35
0-3 months	Physical functioning	55	58
	Role limitation due to physical problems	0	25
	Role limitation due to emotional problems	50	50
	Social functioning	72	64
	Mental health	86	76
	Energy and vitality	68	56
	Pain	67	63
	General health perception	60	54
4-12 months	Physical functioning	75	57
	Role limitation due to physical problems	0	29
	Role limitation due to emotional problems	100	62
	Social functioning	44	48
	Mental health	60	64
	Energy and vitality	50	51
	Pain	44	52
	General health perception	40	37
>12 months	Physical functioning	80	77
	Role limitation due to physical problems	100	66
	Role limitation due to emotional problems	100	67
	Social functioning	89	84
	Mental health	72	74
	Energy and vitality	55	66
	Pain	89	84
	General health perception	50	53

Table 3.4.9: Patients EORTC-30 domains scores at different times

Preoperative stage	Global health status	50	50
	Physical functioning	93	93
	Role functioning	100	100
	Emotional functioning	58	58
	Cognitive functioning	83	83
	Social functioning	100	100
	Fatigue	67	67
	Nausea and vomiting	0	0
	Pain	67	67
	Dyspnoea	33	33
	Insomnia	67	67
	Appetite loss	33	33
	Constipation	0	0
	Diarrhoea	0	0
	Financial difficulties	0	0
0-3 months stage	Global health status	67	65
	Physical functioning	80	77
	Role functioning	67	52
	Emotional functioning	92	79
	Cognitive functioning	83	83
	Social functioning	83	65
	Fatigue	56	44
	Nausea and vomiting	17	19
	Pain	33	33
	Dyspnoea	0	7
	Insomnia	0	26
	Appetite loss	33	44
	Constipation	0	7
	Diarrhoea	0	26
	Financial difficulties	33	37
4-12 months stage	Global health status	50	50
	Physical functioning	73	70
	Role functioning	50	52
	Emotional functioning	58	63
	Cognitive functioning	67	76
	Social functioning	42	42
	Fatigue	44	41
	Nausea and vomiting	0	28
	Pain	33	38
	Dyspnoea	0	29
	Insomnia	67	52
	Appetite loss	67	57
	Constipation	33	38
	Diarrhoea	0	24
	Financial difficulties	33	19
>12 months stage	Global health status	67	74
	Physical functioning	93	82
	Role functioning	100	88
	Emotional functioning	83	83
	Cognitive functioning	100	89
	Social functioning	100	83
	Fatigue	22	23
	Nausea and vomiting	0	5
	Pain	17	14
	Dyspnoea	0	3
	Insomnia	33	39
	Appetite loss	0	15
	Constipation	0	9
	Diarrhoea	0	12
	Financial difficulties	0	18

Table 3.4.11: Patients EORTC H&N35 domains scores at different times

Preoperative stage	Pain	67	67
	Swallowing	50	50
	Senses problems	0	0
	Speech problems	33	33
	Trouble with social eating	50	50
	Trouble with social contact	0	0
	Less sexuality	.	.
	Teeth	33	33
	Opining mouth	67	67
	Dry mouth	0	0
	Sticky saliva	0	0
	Coughing	67	67
	Felt ill	33	33
	Pain killer	100	100
	Nutritional supplements	0	0
	Feeding tube	0	0
	Weight loss	0	0
	Weight gain	100	100
0-3 months stage	Pain	8	33
	Swallowing	42	40
	Senses problems	0	15
	Speech problems	33	29
	Trouble with social eating	33	33
	Trouble with social contact	0	27
	Less sexuality	42	47
	Teeth	0	14
	Opining mouth	0	30
	Dry mouth	33	41
	Sticky saliva	33	46
	Coughing	17	33
	Felt ill	0	11
	Pain killer	100	78
	Nutritional supplements	100	78
	Feeding tube	100	56
	Weight loss	0	22
	Weight gain	0	0

Table 3.4.11: Patients EORTC H&N35 domains scores at different times

4-12 months stage	Pain	50	52
	Swallowing	8	31
	Senses problems	33	42
	Speech problems	44	46
	Trouble with social eating	75	71
	Trouble with social contact	13	22
	Less sexuality	50	53
	Teeth	33	39
	Opining mouth	83	67
	Dry mouth	67	57
	Sticky saliva	100	57
	Coughing	33	33
	Felt ill	33	33
	Pain killer	100	86
	Nutritional supplements	100	71
	Feeding tube	0	43
	Weight loss	100	57
	Weight gain	0	0
>12 months stage	Pain	17	15
	Swallowing	8	17
	Senses problems	0	15
	Speech problems	28	27
	Trouble with social eating	8	23
	Trouble with social contact	7	13
	Less sexuality	33	37
	Teeth	0	27
	Opining mouth	33	39
	Dry mouth	33	48
	Sticky saliva	0	27
	Coughing	33	21
	Felt ill	0	6
	Pain killer	0	36
	Nutritional supplements	0	27
	Feeding tube	0	9
	Weight loss	0	9
	Weight gain	0	18

Glossary

SF-36 domains:

PF: Physical functioning

RP: Role limitation due to physical problems

RE: Role limitation due to emotional problems

SF: Social functioning

MH: Mental health

EV: Energy/Vitality

P: Pain

GH: General health perception

CH: Change in health

EORTC-C30 domains

QL2: Global health status

PF2: Physical functioning (revised)

RF2: Role functioning (revised)

EF: Emotional functioning

CF: Cognitive functioning

SF: Social functioning

FA: Fatigue

NV: Nausea and vomiting

PA: Pain

DY: Dyspnoea

SL: Insomnia

AP: Appetite loss

CO: Constipation

DI: Diarrhoea

FI: Financial difficulties

The EORTC H&N35

HNPA: Pain

HNSW: Swallowing

HNSE: Senses problems

HNSP: Speech problems

HNSO: Trouble with social eating

HNSC: Trouble with social contact

HNSX: Less sexuality

HNTE: Teeth

HNOM: Opening mouth

HNDR: Dry mouth

HNSS: Sticky saliva

HNCO: Coughing

HNFI: Feeling ill

HNPK: Pain killer

HNNU: Nutritional supplements

HNFE: Feeding tube

HNWL: Weight loss

HNWG: Weight gain